PROPARGITE
(OMITE)

RISK CHARACTERIZATION DOCUMENT

Medical Toxicology and Worker Health and Safety Branches

DEPARTMENT OF PESTICIDE REGULATION

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

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PROPARGITE

SUMMARY

2-[4-(1,1-Dimethylethyl)phenoxy]cyclohexyl 2-propynyl sulfite (propargite) was first registered in 1969 as a miticide (U.S. EPA, 2001a). U.S. EPA issued a Registration Standard for propargite in 1986. In 1996, U.S. EPA and the registrant signed an agreement to voluntarily cancel certain uses due to unacceptable carcinogenicity dietary risk. In September 2001, U.S. EPA finalized their Reregistration Eligibility Document (RED) which resulted in proposed mitigation for worker exposure including changes in the packaging of some formulations, increased protective equipment (e.g., gloves, closed mixing systems, enclosed cabs and cockpits) and increased restricted entry intervals (REIs).

Propargite is an organosulfur miticide/acaricide whose pesticidal mechanism of action involves the inhibition of magnesium-stimulated ATPase. Its primary mechanism of toxicity in mammals involves local irritation at the site of contact. With acute exposure by the inhalation route, labored breathing, nasal discharge, moist rales, reduced body weights and reddening of the lungs were observed. With acute oral exposure to propargite, gastrointestinal abnormalities, dark red adrenal glands, bright red lungs, jaundice, red and swollen paws, mouth and urogenital area, decreased urination, abnormal defecation and reduced body weights were seen. With acute dermal exposure, severe dermal irritation was observed along with vocalization, abnormal defecation, and inappetance. Maternal effects seen within the first few days of exposure and fetal effects were considered in selecting the acute NOEL. Maternal effects after a few days (e.g., diarrhea, soft stools, anorexia, urinary incontinence, abnormal respiration) were similar to those observed with a single oral dose. Developmental effects included abortions, resorptions, reduced fetal viability, minor skeletal variations related to delayed ossification, malaligned or fused sternebrae, hydrocephaly and reduced pup weight. The lowest NOEL observed with acute or short-term exposure to propargite was 2 mg/kg/day based on anorexia in pregnant rabbits and delayed ossification in rabbit fetuses.

The most common systemic effect with subchronic exposure to propargite, regardless of route, was reduced body weights. Reductions in food consumption were also seen. Changes in hematological and clinical chemistry values (↓ serum albumin and calcium, ↑ serum globulin, ↑ WBC count, segmented neutrophils, monocytes and platelets) were observed in a dermal study in rabbits. The veterinary pathologist for this study suggested that the hematological and clinical chemistry changes may be related to the dermal irritation. Increased relative liver, kidney, adrenal gland and/or gonad weights were observed in several studies. It is unclear if these organ weight changes are related to reduced body weights or organ toxicity. Pathological findings in these subchronic studies included increased pigment in reticuloendothelial cells of the liver and hemosiderosis of the spleen in dogs and chronic nephritis, liver inflammation and necrosis in rabbits. The lowest systemic NOEL in an acceptable subchronic toxicity study was 1 mg/kg/day based on reduced body weights (F: 14-20%), changes in clinical chemistry and hematology values, and increased relative liver and kidney weights in rabbits after a 21-day dermal exposure. No seasonal exposure to propargite is anticipated since dietary and drinking water exposure to propargite did not vary significantly with season. Consequently, a subchronic NOEL was not selected for propargite.

Several developmental and reproductive effects were seen in repeated dosing studies. These effects included increased abortions, increased resorptions, reduced fetal viability, delayed ossification, malaligned or fused sternebrae, hydrocephaly and reduced body weights. The NOELs for fetal or pup effects were equal to or higher than the maternal or parental NOELs, suggesting there is no increased pre- or post-natal sensitivity to propargite.

The effects observed in laboratory animals with chronic exposure to propargite were similar to those observed with subchronic exposure, including reductions in body weights and food consumption, and changes in clinical chemistry, hematological values and organ weights. The lowest NOEL in a chronic study of acceptable quality was 3.8 mg/kg/day based on reduced body weights and food consumption in rats fed propargite in the diet for 2 years.

There is evidence that propargite is oncogenic based on an increase in undifferentiated sarcomas of the jejunum in Sprague-Dawley rats. DPR considered propargite to be oncogenic because 1) jejunal sarcomas are a rare tumor type; 2) sarcomas of the intestine and other tissues were observed in two other supplemental studies; and 3) there was a shortening of the time to tumor. There was some evidence to suggest that propargite may be acting by a threshold mechanism: 1) transient increase in cell proliferation and 2) essentially all negative genotoxicity studies. However, by itself, this evidence was not considered sufficient to justify using a threshold approach. Therefore, a non-threshold mechanism was assumed as a default. Although there was a dose-related increase in deaths at the high dose, which suggests that the Weibull time-to-tumor model would be the most appropriate model to estimate oncogenic potency, the registrant showed that the Weibull time-to-tumor model was not the best model to use based on its poor fit. Apparently, the poor fit with the Weibull time-to-tumor model was due to its inability to optimize the model parameters. Therefore, DPR elected to use a multistage linear model, Global86, to estimate the oncogenic potency of propargite. The estimated oncogenic potency for propargite ranged from 5.9×10^{-3} $(mg/kg/day)^{-1}$ for the maximum likelihood estimate (MLE) to 2.6×10^{-2} $(mg/kg/day)^{-1}$ for the 95th percent upper bound (95% UB).

A tiered approach was used in the dietary exposure analysis for propargite. Due to the small number of DPR samples monitored for propargite, the residue values for most commodities came from PDP's monitoring programs from 1995 to 2001. When sufficient data were available (i.e., > 30 samples), PDP data from California was used exclusively since they usually had a lower limit of quantitation (LOQ). Monitoring data from appropriate surrogate crops were used if none were available for a given commodity. If no monitoring data were available, residue data from field trial studies were used when available. The acute residue value was the highest detected residue value if a point estimate was used or a residue value from a distribution if there were a sufficient number of samples to do a Monte Carlo analysis. For the chronic dietary assessment, point estimates were used for all the commodities with the chronic value set at the mean or average residue level. If there were no residues detected, then the residue level is set at the LOQ for acute exposure and ½ of the LOQ for chronic exposure. If no monitoring data, surrogate data or field trial data were available, then the residue values were set at the tolerance level for acute exposure and ½ of the tolerance level for chronic exposure. The dietary exposure was further refined by taking the percent crop treated (PCT) into consideration whereby some of the samples with non-detectable residues were set to zero. Dietary consumption of commodities by various population subgroups was based on USDA Continuing Survey of Food Intakes by Individuals (CSFII) from 1994 to 1998. The acute dietary exposure

estimates for propargite ranged from 1.66-6.81 µg/kg/day using primarily PDP monitoring data. The estimated chronic dietary exposure dosages ranged from 0.07 to 0.59 µg/kg/day. The population subgroup with the highest acute and chronic dietary exposure was children 1 to 6 years old.

No propargite residues have been detected in well water monitored by DPR between 1984 and 1991; however, they have been detected in surface water samples collected in California between 1993 and 1998. Drinking water exposure dosages were based on DPR's surface water monitoring data. The estimated acute drinking water exposure to propargite ranged from 0.34 to 2.34 µg/kg/day. The estimated chronic drinking water exposure ranged from 0.002 to 0.012 µg/kg/day. Non-nursing infants also had the highest estimated acute and chronic exposure to propargite in drinking water.

When dietary and drinking water exposure to propargite were combined, the acute aggregate exposure ranged from 1.80 to 6.80 µg/kg/day. The aggregate chronic exposure to propargite ranged from 0.07 to 0.60 µg/kg/day. Children 1 to 6 years old had the highest acute and chronic aggregate exposure.

The risk for non-oncogenic health effects is expressed as a margin of exposure (MOE) which is the ratio of the NOEL from the animal study to the human exposure dosage. Generally, an MOE of at least 100 is desirable assuming that humans are 10 times more sensitive than animals and that there is a 10-fold variation in the sensitivity between the lower range of the normal distribution of the overall population and the sensitive subgroup. The MOEs for acute dietary exposure to propargite in the various population subgroups ranged from 290 to 1,200. The MOEs for chronic dietary exposure ranged from 6,300 to 51,000. The MOEs for acute drinking water exposure to propargite ranged from 850 to 5,800. The MOEs from chronic drinking water exposure ranged from 330,000 to greater than 1,000,000. The MOEs for acute aggregate exposure to propargite in the diet and drinking water ranged from 290 to 1,200. The MOEs for chronic aggregate exposure ranged from 6,300 to 51,000.

The negligible carcinogenic risk level is generally considered one excess cancer case in a million people. The estimated carcinogenic risk from dietary exposure to propargite ranged from 1.1 (maximum likelihood estimate) to 4.7 (95^{th} percentile upperbound) excess cancers in a million people. The estimated carcinogenic risk from drinking water exposure to propargite ranged from 1.6 to 6.8 excess cancers in a 100 million people. The estimated carcinogenic risk from aggregate exposure to propargite in the diet and drinking water ranged from 1.1 to 4.8 excess cancer cases in a million people.

A tolerance assessment for propargite was conducted assuming commodities were consumed at their tolerance level for acute exposure. The MOEs for potential acute effects were less than 100 for some or all population subgroups for oranges, grapes, grapefruit and nectarines. Based on these estimates, the tolerances for these commodities should be reviewed.

I. INTRODUCTION

A. REGULATORY BACKGROUND

2-[4-(1,1-Dimethylethyl)phenoxy]cyclohexyl 2-propynyl sulfite (propargite) was first registered in 1969 as a miticide (U.S. EPA, 2001a). U.S. EPA issued a Registration Standard for propargite in 1986. In 1995, U.S. EPA issued a data call-in. In 1996, U.S. EPA and the registrant signed an agreement to voluntarily cancel certain uses including its use on apricots, apples, peaches, pears, plums, figs, cranberries, strawberries, green beans, and lima beans. These uses were eliminated due to unacceptable carcinogenicity dietary risk. In July 2000, U.S. EPA had a conference call with USDA, the registrant and stakeholders to discuss risk concerns. U.S. EPA incorporated information from this call in their Reregistration Eligibility Document (RED) that they finalized in September of 2001. At the same time the RED was finalized, U.S. EPA held a close-out conference call with many of the same participants from the July 2000 conference call to discuss proposed mitigation which included changes in the packaging of some formulations, increased protective equipment (e.g., gloves, closed mixing systems, enclosed cabs and cockpits) and increased restricted entry intervals (REIs).

The purpose of this current risk assessment is to address the potential adverse health effects for the general public exposed to propargite through dietary and drinking water exposure. An addendum to this risk assessment document will be prepared at a later date to address occupational exposure for agricultural workers and, depending on the availability of air monitoring data, ambient air exposure for the general public. An aggregate risk assessment will be included in the addendum to address combined exposure to propargite through diet, drinking water, occupation and possibly ambient air.

B. CHEMICAL IDENTIFICATION

Propargite is an organosulfur miticide/acaricide for controlling mites on a variety of bearing and non-bearing agricultural crops, as well as non-food agricultural sites (U.S. EPA, 2001a). Its pesticidal mechanism of action involves the inhibition of magnesium-stimulated ATPase (IRAC, 2002). It primary mechanism of toxicity in mammals involves local irritation at the site of contact.

C. TECHNICAL AND PRODUCT FORMULATION

The only registrant for propargite is Uniroyal Chemical Company. It is registered under the trade names Omite or Comite. Currently, there are 6 actively registered products in California. Three are soluble or wettable powders with a propargite concentration of 32% (Omite-30W, Omite-30WS and Omite-CR). Two others are emulsifiable concentrates with propargite concentrations of 26.4% (Comite) and 30.8% (Omite-6E). The other product is Omite Technical with a propargite concentration of 90.6%.

D. USAGE

Propargite may be sprayed on crops by ground or air application. Chemigation is not allowed. In 2002, 977,039 lbs. of propargite were applied. Most of the use was on corn (field and sweet, 37%), grapes (table and wine, 14%), walnuts (10%), cotton (6%), beans (dried, succulent and unspecified, 3%) and nectarines (2%).

E. PHYSICAL AND CHEMICAL PROPERTIES (Agrochemical Handbook, 1992)

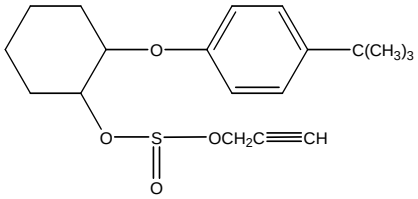
1. Common Name: Propargite

2. Chemical Name: 2-(4-(1,1-Dimethylethyl)phenoxy)cyclohexyl 2-propynyl sulfite

3. Trade Names: Omite®, D-014®, BPPS®, Comite®

4. CAS Registry No.: 2312-35-8

5. Structural Formula:



6. Empirical Formula: $C_{19}H_{26}O_4S$

7. Molecular Weight: 350 g

8. Specific Gravity : 1.085 – 1.115 g/ml

9. Physical Form: Dark reddish-brown viscous liquid

10. Solubility: Water at 25°C: 1.93 µg/ml (McManus and Spare, 1987)
Acetone at 25°C: > 1 g/ml
Hexane at 25°C: > 1 g/ml

11. Vapor pressure: 4.49×10^{-8} mmHg at 25°C (Schofield and Blasberg, 1989)

12. Octanol/water partition coefficient: 5313 (log K_{ow} = 3.66) at 25°C (Smilo, 1986)

13. Henry's law constant: 1.088×10^{-8} atm-m^3/mol at 25°C
(Schofield and Blasberg, 1989)

F. ENVIRONMENTAL FATE

Summary

Air: Propargite has very negligible vapor pressure, therefore, it is not readily volatilized into the atmosphere. However, based on its very low vapor pressure, greater than 80% of propargite could become associated with particulate matter in the air (Bidleman, 1988). This particle associated propargite could exist in the air for days and travel over a great distance. The low Henry's law constant indicates that propargite is unlikely to volatilize into air from an aqueous solution. The low Henry's law constant also suggests that most of the propargite would be washed out of the air by rain during the winter months in California.

Water: Propargite is an extremely hydrophobic compound with very low water solubility. Its organic adsorption coefficient (K_{oc}) values indicate that propargite moderately binds to soils with low organic matter (OM) content and strongly binds to soils with rich OM content. It also has a high octanol/water partition coefficient suggesting that this compound readily binds to soils and other suspended matters in water. Therefore, propargite has a low potential to leach in soil and reach ground water. Propargite was not detected in well monitoring conducted in California between 1984 and 1991. However, propargite was found in approximately 10% of the surface water samples tested in California between 1993 and 1998.

Soil: The fate of propargite in soil can be affected by many factors including its physical-chemical properties, application rate, soil type, moisture content, climate and runoff. The K_{oc} values of propargite suggest that propargite moderately binds to soil particles and strongly to soils with rich organic contents. The photodegradation half-life of propargite on a sandy loam soil is approximately 75 days. The anaerobic metabolism half-lives for propargite ranged from 4.5 to 12 months. Under aerobic conditions, the half-life is 40 days. In field dissipation studies, no residues were detected below 6 inches and the estimated half-lives ranged from 64 to 122 days, indicating that propargite is moderately persistent in soil.

Hydrolysis

The hydrolysis half-lives of propargite are pH dependent. Experiments were conducted at concentrations of 0.6-0.7 ppm at 25°C (Nowakowski, 1987a). The half-lives at pH 5, 7 and 9 were 120, 78 and 3 days, respectively, when the concentration of tetra-n-butylammonium phosphate buffer was 0.5 M. When the buffer concentration was 0.005M, the half-lives at pH 5, 7 and 9 were 702, 48, and 2 days, respectively. The only identified hydrolysis product was 2-[4-(1,1-dimethylethyl)phenoxy]-cyclohexanol (propargite glycol ether).

Photolysis

Aqueous photolysis studies on propargite were performed at 0.97 ppm and pH 5, which was the most stable pH of those tested for hydrolysis (Nowakowski, 1987b). Samples were exposed to natural sunlight for 12 hours every day. The observed photolysis half-life was approximately 134-140 days. This result was almost identical to the result obtained from an aqueous dark control, meaning that hydrolysis is the major degradation pathway for propargite in

water as opposed to photolytic degradation. The identified degradation products were propargite glycol ether and *p*-*t*-butylphenol.

Soil photolysis of Omite was investigated on a sterilized sandy loam soil using a Xenon arc burner over 15 days (Korpalski, 1990). The estimated soil photolysis half-life for Omite was 75 days and the only identified degradate was glycol ether.

Soil Metabolism

The aerobic soil metabolism of 4.9 ppm [^{14}C]Omite was investigated on sandy clay loam in darkness at 25°C (Dzialo, 1988). After 90 days, 31% of applied radioactivity was extractable from the soil, of which 77% was unreacted propargite. Thirty percent of the original radioactivity was found to be bound residues and another 31% was converted to carbon dioxide. The estimated half-life of Omite under aerobic conditions was 40 days.

Anaerobic soil metabolism of [^{14}C]Omite was studied at concentrations of 1 and 10 ppm on sandy loam soil (Meck and Campbell, 1977). The half-lives of 1 and 10 ppm Omite were approximate 4.5 months and 12 months, respectively. The major degradation product was glycol ether. Large amounts of bound residues were also found in the study.

Soil Adsorption

A batch soil adsorption/desorption study on Omite was conducted on four soils: a Wisconsin potato soil (OM 0.71%, pH 6.7), a California sand (OM 0.30%, pH 7.7), a Hesperia sandy loam (OM 1.70%, pH 6.9) and a clay loam (OM 5.36%, pH 6.3) (Korpalski and Nowakowski, 1988). The 48 hours K_d values was experimentally obtained via ^{14}C measurements. The soil adsorption coefficient values (K_d) were 17, 11, 55 and 266 for potato soil, sand, sandy loam and clay loam, respectively. Their organic adsorption coefficient values (K_{oc}) were 4128, 6322, 5578 and 8553 cm^3/g, respectively. These data showed that propargite moderately binds to soils of low OM content and strongly bind to soils of high OM content.

Soil Dissipation

Field dissipation tests have been performed for propargite in many locations and conditions. Propargite and glycol ether residues did not penetrate to below 6 inches in tested sites (Korpalski and Nowakowski, 1988; Harned, 1989). Comite was applied at a rate of 4.1 lbs a.i. per acre in a cotton field situated in Kerman, California (Harned, 1989). The soil type was a sandy loam (OM 0.7%, pH 7.9) and the total rainfall during this period was 49 inches. After 1, 4, 7, and 14 days and 1, 2, 3, 4, 6, 9, 12 months of application, soil was sampled for analysis. The propargite residues in the top 6 inches ranged from 0.22 ppm to 0.54 ppm during the first 4 months of the study. After 6 months, residues in all soil samples were below the minimum detection level of 0.10 ppm and no residues were found below 6 inches.

In another experiment, Omite 30W was applied onto two unplanted sites in California to investigate the dissipation of propargite and its metabolite glycol ether in soils (Lengen, 1989). The total rainfall was 8-9 inches during the study and the application rate was 4.5 lb active ingredient per acre. The monitoring period was 375 days. Propargite was only found in the top

6 inches of soil on both sites with residues ranging from 5.35 to 0.14 ppm on first site and 2.23 to 0.14 ppm on second site. The estimated half-lives in first and second site were 64-100 and 83-122 days, respectively. Propargite glycol ether was only detected in the top 6 inches with the concentrations from 0 to 0.35 ppm and from 0 to 0.30 ppm on first and second site, respectively.

Surface Water Monitoring

Although propargite has low water solubility and medium to high soil adsorption, its relatively long soil dissipation half-lives make it a possible contaminant for surface water. From January 1993 through August 1998, 295 samples were examined for propargite in California and there were 15 detections ranging from 0.018 to 20 parts per billion (ppb) with a limit of quantitation of 0.013 ppb (Starner, 2003). The estimated 95th percentile for the residues was 2.42 ppb and the mean residue level was 0.089 ppb.

Groundwater Monitoring

Propargite has low water solubility and medium to high soil adsorption. DPR does not consider propargite a potential groundwater contaminant since its physicochemical properties do not exceed the specific numerical values (SNVs) for solubility (SNV>3 ppm), K_{oc} (SNV <1,900 cm^3/g), hydrolysis (SNV > 14 days) or aerobic and anaerobic soil metabolism (SNVs > 610 and 9 days, respectively) (DPR, 2000a). Of 405 wells sampled for propargite in California during 1984 through 1991, no detection was reported at minimum detection levels ranging from 0 to 80 ppb (DPR, 2000b).

II. TOXICOLOGY PROFILE

A. PHARMACOKINETICS

Summary

The oral absorption of propargite was estimated to be approximately 40% in rats and mice based on a bioavailability study using plasma concentration curves with oral and intravenous administration. This estimate is similar to the amount of propargite excreted in the urine and bile in several elimination studies (20-40%). The elimination studies were not used to estimate oral absorption because either the recovery was low or the bile duct was not cannulated. Dermal absorption in rats varied with the formulation and concentration of propargite ranging from 3 to 20%. The elimination half-lives were between 8 and 11 hrs for rats and mice, respectively. The proposed metabolic pathway for propargite involves the hydrolysis of the propynyl sulfite side chain of propargite and the subsequent oxidation of the tert-butyl moiety and hydroxylation of the cyclohexyl moiety. After oral administration, the majority of propargite appears to be excreted unabsorbed, ranging from 33% to 64%, depending on the species and the amount administered. The amount excreted in the bile also varied with the dosage and species, ranging from 0.1% to 16% . The amount of propargite in the urine did not vary as much, ranging only between 4 and 11%.

Absorption

Oral: A pharmacokinetic study was conducted in both sexes of Sprague-Dawley rats and CD-1 mice following a single oral dose (150 mg/kg) or intravenous dose (20 mg/kg) of ^{14}C-propargite (Gay, 1994). Blood samples were collected at 30 minutes, and 1, 2, 4, 8, 12, 24, 36 and 48 hours after oral administration and 2, 5, 10, 15 and 30 minutes, and 1.5, 4, 12, 24 and 48 hours after intravenous administration. Although blood samples were taken only during the first 48 hours, the area under the plasma concentration curve was extrapolated out to infinity. Oral bioavailability was calculated by comparing the area under the plasma concentration curve with oral and intravenous administration after normalizing for dose and clearance. Using this formula, the investigators estimated the oral bioavailability was approximately 80% in rats and 75% in mice. However, this estimate of oral absorption appears to be in conflict with the urinary, biliary, and fecal excretion data which suggest that a large portion of propargite (45-75%) is excreted by rats in the feces, especially at high doses, possibly as unabsorbed material (see Excretion section). In some elimination studies the recoveries were less than 100%, probably because the blood or excreta were only monitored for 24 to 48 hours after dosing. Also, in a couple of these elimination studies, the bile duct was not cannulated, so it is unclear how much of the radioactivity in the feces is absorbed material. However, a more likely explanation for the contradictory results between the bioavailability study and the elimination studies, is that bioavailability was calculated incorrectly due to a “flip-flop” phenomenon (Gilbaldi and Perrier, 1982). The slopes for the elimination rates with oral and intravenous administration should be parallel. However, in the “flip-flop” situation, the elimination rate is slower with oral administration than intravenous administration indicating that oral absorption is the rate limiting step during the elimination phase. Consequently, estimates of clearance are not considered accurate in this situation. In this case, it is more accurate to estimate bioavailability without taking clearance into consideration. When calculated this way, the bioavailability

ranged from 35.5% in female rats to 53.6% in female mice. This is more consistent with the eliminations studies. The oral absorption was assumed to be 40% based on an average estimated bioavailability of 42% in rats and mice.

Dermal: Two sets of dermal absorption studies of various propargite formulations (Omite technical, Omite 30W, Omite 6E and Comite) were conducted in male Sprague-Dawley rats at 0.05, 0.5 and 5.0 mg/kg (Chadwick, 1989a-c; Andre et al., 1989&1990a-c; Mizens et al., 1990). These dosages correspond to concentrations of 1, 11 and 112 μg/cm^2, respectively, based on an application site of 10 cm^2. The test material was left on the application sites for 2, 4, 8 or 24 hours with 4 rats used for each exposure period. In the first set of studies, the dermal absorption for the various formulations (Comite, Omite 6E and Omite 30W) after the 24-hour exposure ranged from 3 to 17% after correction for recovery (Chadwick, 1989a-c; Andre et al., 1989). The lowest dermal absorption was with the Omite 30W formulation at 5.0 mg/kg. The highest dermal absorption was with Comite at 0.05 mg/kg. In the second set of experiments, the corrected dermal absorption of the various formulations (Omite technical, Omite 30W, Omite 6E and Comite) ranged from 6 to 20% (Andre et al., 1990a-c; Mizens et al., 1990). The lowest dermal absorption was with Omite 6E at 5.0 mg/kg and Comite at 0.5 mg/kg. The highest absorption was observed with the technical material at 0.05 mg/kg.

Distribution

In the pharmacokinetic study conducted by Gay (1994), the plasma concentration curve after oral administration best fit a one-compartment model for both species and sexes with first-order oral absorption and elimination. The C_{max} values were 11.4, 9.34, 14.3 and 11.7 μg/mL for male rats, females rats, male mice and female mice, respectively. The T_{max} values ranged from 4 to 8 hours for rats and 2 to 4 hours for mice. The elimination half-life ($\beta\ t_{1/2}$) ranged from 10 to 11 hours for rats and 8 to 9 hours for mice. After intravenous administration, the plasma concentration curve best fit an open two-compartment model for both species and sexes with a first order elimination phase. The distribution half-life ($\alpha\ t_{1/2}$) ranged from 11 to 24 minutes for both species and sexes. The elimination half-lives were 4, 2 and 5.5 hours for both sexes of rats, male mice and female mice, respectively. The area under the concentration curve was two-fold greater for rats than mice. Clearance values were approximately 4 and 9 mL/min/kg for rats and mice, respectively. The volume of distribution (V_d) values ranged from 0.5 to 0.7 L/kg, which was similar to the total body water volumes, indicating distribution of propargite throughout the body.

The pharmacokinetics of propargite were also evaluated in another study where rats and mice had their bile ducts and duodenum cannulated (Gay, 1994). A single oral dose of ^{14}C-propargite was administered to 5 rats and 5 mice per sex at 150 mg/kg. The bile was collected at 1, 2, 4, 8, 12, 24, 36 and 48 hours. While bile was collected, an infusion pump delivered replacement bile salt via the duodenal cannula. The area under the concentration curve (AUC), C_{max}, T_{max}, and $t_{1/2}$ were estimated for the bile concentration curve. No gender-related differences in the bile elimination parameters were seen in either species. The values for AUC and C_{max} were greater for mice (11639 μg-equiv./g x h and 713 μg-equiv./g, respectively) than rats (8836 μg-equiv./g x h and 326 μg-equiv./g, respectively) while the $t_{1/2}$ was less (9.2 hrs vs. 21.4 hrs).

Biotransformation

Banijamali and Tortora (1988a) conducted a study in which male rats were administered 1.5 g/kg of ^{14}C-propargite (labeled on the phenyl ring). Urine and feces were collected for 72 hours. Five major metabolites in urine were identified: 1-[4-(2,x-dihydroxycyclohexoxy)-phenyl]-2,2-dimethyl acetic acid (Metabolite #1), 1-[4-(2,x-dihydroxycyclohexoxy)phenyl]-2,2-dimethylethyl sodium sulfate (Metabolite #2), 1-[4-(1,1-dimethyl-2-hydroxyethyl)phenoxy]-2,4,5-cyclohexane-triol (Metabolites #3), 1-[4-(1,1-dimethyl-2-hydroxyethyl)phenoxy]-2,x,x′-cyclohexane-triol (Metabolites #4) and 1-[4-(1,1-dimethyl-2-hydroxyethyl)phenoxy]-2,x-cyclohexane-diol (Metabolite #5). Based on these urinary metabolites, these investigators proposed a metabolic pathway for propargite shown in Figure 1. In a subsequent study, Banijamali and Nag (1990) identified fecal metabolites in rats administered a single oral dose of ^{14}C-propargite at 1) 25 mg/kg, 2) 25mg/kg after 14 days of administration of unlabeled propargite at 25 mg/kg/day and 3) 200 mg/kg. The metabolites included 1-[4-(1,1-dimethylethyl)phenoxy]-2-cyclohexanol (propargite glycol ether), Metabolite #1, Metabolite #3 and Metabolite #5.

The metabolism of propargite was evaluated *in vitro* and *in vivo* in female rats, rabbits, and monkeys due to apparent differences in toxicity (Doweyko and Tortora, 1989). The oral LD_{50} was reported to be significantly lower in rabbits than in rats and monkeys. The *in vitro* metabolism was evaluated by incubating liver homogenates and S-9 preparations with ^{14}C-propargite (labeled on the phenyl ring) at 8 and 80 nmol/mL. Three major components were observed in all analyses: the parent compound, propargite glycol ether and propargite bis-glycol ether sulfite. Two polar metabolites representing oxidation products were also present in all samples. No clear species differences in metabolism were seen. The *in vivo* metabolism was evaluated by analyzing urinary, biliary and liver metabolites after oral administration of ^{14}C-propargite at 18 mg/kg (4 rabbits, 2 monkeys) or 105 mg/kg (4 rats, 2 monkeys). Half of the animals for each species were placed in metabolism cages and excreta were collected. Selected tissues were also collected at the end of the 24-hour in-life period. The other half of the animals had a cannula inserted in the bile duct and had bile collected. Only liver samples were taken from these animals at the end of the 24-hour in-life period. It appears the rabbit tends to produce less polar metabolites than the rat or monkey. In addition, some unique metabolites were found, but their significance is unknown.

Plasma and bile samples from rats and mice were analyzed for metabolites by Gay (1994). Metabolism was rapid and extensive with similar metabolite profiles in both species. No parent compound was found in the bile of either species at any collection period. The parent compound was found in the plasma at less than 4% of the radioactive residue except in male mice which had approximately 10%. Generally, the proportion of more polar biliary metabolites increased with time. Six metabolites were detected in the biliary samples. Metabolites #1, #3 and #5 were identified. The biliary metabolites were reported to be similar to urinary metabolites identified in another study, except for two metabolites which were tentatively identified as different hydroxy-cyclohexyl isomers of TBPC. Four major metabolites were identified in plasma. The major plasma metabolite was 1-[4-(1,1-dimethyl-2-hydroxyethyl)phenoxy]-2-cyclohexanol or hydromethyl-TBPC. Metabolite #5 was also prominent in all the plasma samples. It was proposed that the plasma and biliary metabolites of propargite are the result of hydrolysis of the

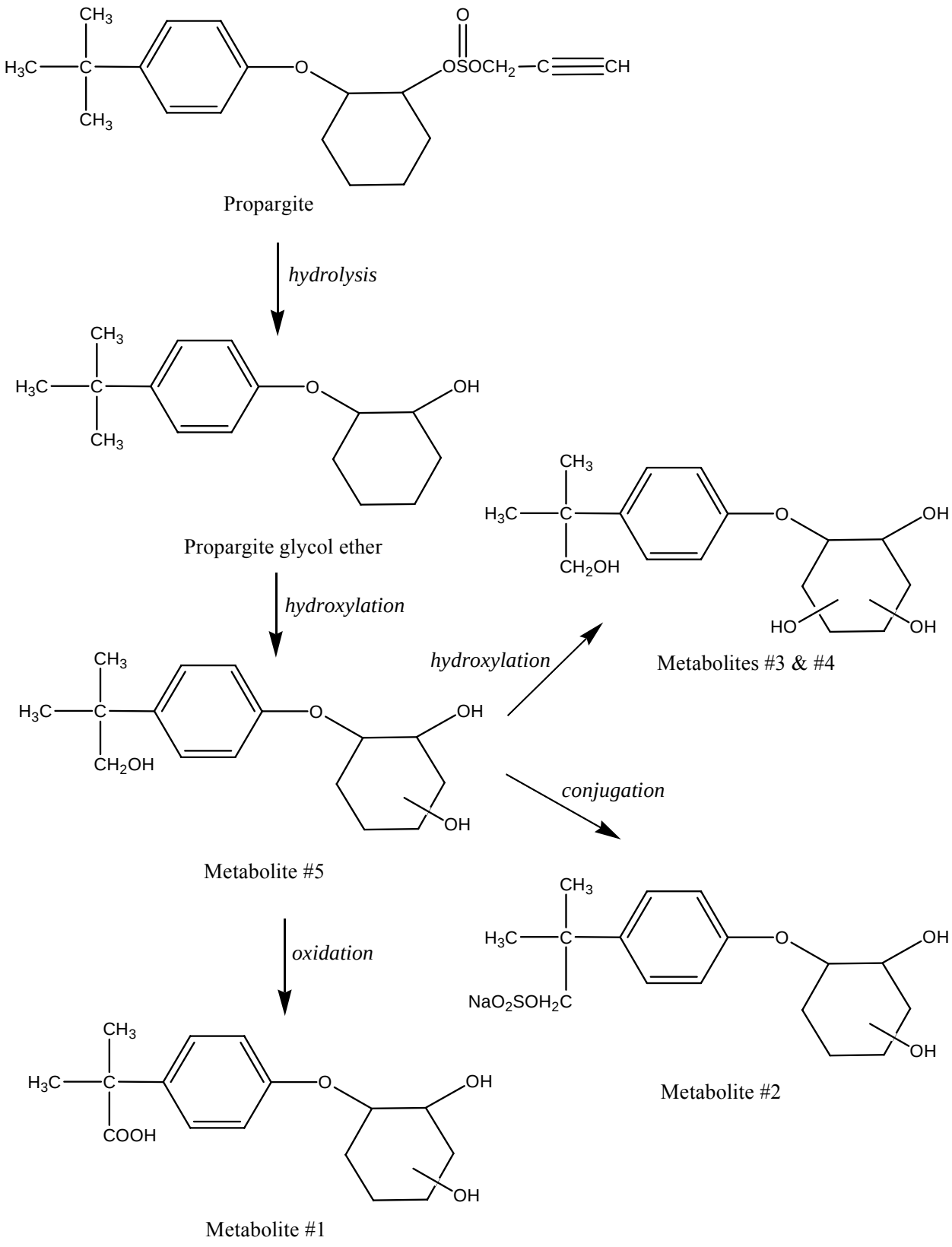


Figure 1. Proposed metabolic pathway for propargite (Banijami and Tortora, 1988).

propynyl sulfite side chain of propargite and the subsequent oxidation of the tert-butyl moiety and hydroxylation of the cyclohexyl moiety.

An additional metabolism study analyzed the metabolites of the 2-propynyl sulfite side chain of propargite (Banijamali and Fang, 2000). [1,2,3-^{13}C, 2,3-^{14}C-Propargyl]Propargite was administered to male rats and mice at 150 mg/kg. Six major urinary metabolites were isolated and identified in rats: 2-(acetylamino)-3-(2-propynylthio)-propanoic acid (peak 1), 2-(carboxy-methylthio)-2-propenoic acid (peak 2), 3-(carboxymethylthio)-2-propenoic acid (peak 3), 3-[(2-carboxy-2-hydroxyethyl)thio]-2-propenoic acid (peak 4), 3-(N-formylglutamylcysteinyl)-2-propenoic acid (peak 5), and 2-(N-formylglutamylcysteinyl)-2-propenoic acid (peak 6). Two pathways of metabolism were proposed for propargite in rats based on this study. The first pathway involves direct conjugation of propargite to yield the peak 1 metabolite. The second pathway involves the hydrolysis of the propynyl sulfite side chain to the hypothetical intermediate, 2-propargyl alcohol, presumably followed by its oxidation to 2-propynoic acid. The acid subsequently undergoes conjugation with glutathione with further metabolism to yield the remaining metabolites identified in rats. In feces, 80% of the total radioactive residue (TRR) was the parent compound. The other metabolites isolated were each less than 1% of the TRR. Some of these metabolites were intermediates in the biosynthesis of the urinary metabolites while others were diconjugates, probably formed by the addition of 2 glutathione molecules followed by further degradation, analogous to the pathways described for the urinary metabolites. Seven major urinary metabolites were identified in mice. The first 4 peaks were the same as in rats, but the remaining peaks were different: 3-[(2-acetylamino-2-carboxyethyl)thio]-3-[(2-amino-2-carboxyethyl)thio]-1-propanol (peak 5), 3-[(2-amino-2-carboxyethyl)thio]-2-propenoic acid (peak 6), and 3,3-bis[(2-amino-2-carboxyethyl)thio]-1-propanol (peak 7). Similar metabolic pathways were proposed for mice, except that some metabolites (peaks 5 and 7) were formed from the conjugation of the propargyl alcohol before it underwent further oxidation. In feces, propargite represented 68% of the TRR. The most abundant polar metabolite in mouse feces was 3-(carboxymethylthio)-2-propenoic acid, which represented 1.94% of the TRR. The other 7 fecal metabolites were each less than 1% of the TRR and were closely related to the mouse urinary metabolites.

Excretion

Banijamali and Tortora (1988b) conducted a pharmacokinetic study in which a single oral dose of ^{14}C-propargite was administered at 25, 60 or 200 mg/kg. Urine, feces and blood samples were collected for 96 hours after dosing. Findings from this study were compared with a satellite pharmacokinetic study that was conducted in conjunction with a subchronic toxicity study in which 12 rats/sex/dose were fed unlabeled propargite in the diet for 13 weeks at 100, 1000 or 2000 ppm. After 13 weeks, 2 rats/sex/dose were administered 12.5 μCi of ^{14}C-propargite by oral gavage. With a single dose of propargite, the mean urinary excretion was 40, 37 and 22% of the applied dose at 25, 60 and 200 mg/kg, respectively. The mean fecal excretion was 56, 74 and 73% of the applied dose at 25, 60 and 200 mg/kg, respectively. By comparison, the mean urinary excretion was 28, 34 and 28% after 13 weeks of feeding at 100, 1000 and 2000 ppm, respectively. The mean fecal excretion was 35, 31 and 29% at 100, 1000 and 2000 ppm, respectively. The highest tissue residues in both studies were found in the gastrointestinal tract, liver, muscle, fat and blood, but represented less than 5% of the applied dose at all dose levels. The recovery in the single dose study ranged from 97-114%. The recovery was lower in the

subchronic study with only 68-79% of the radioactivity recovered. The low recoveries were attributed to no fecal or urine samples collected from some rats at certain time points. It is unclear whether the investigators were suggesting the lack of urine or fecal samples at these time points was due to experimental errors or other biological phenomena.

The fecal excretion increased with repeated exposure in another study conducted by Banijamali and Nag (1990). In this study, ^{14}C-propargite was given to rats at 25 mg/kg after pretreatment for 14 days with unlabeled propargite at 25 mg/kg/day. Another group was administered a single dose of ^{14}C-propargite at 25 mg/kg with no pretreatment. The fecal excretion increased from 51.3% to 63.3% of the applied dose in males and 61.2% to 71.7% of the applied dose in females with repeated exposure. As with the previous study, these investigators also found that the fecal excretion increased with dose. After administering a single dose of ^{14}C-propargite at 200 mg/kg, 74.5% and 69.9% of the applied dose was excreted in the feces by males and females, respectively.

In the comparative metabolism study in rats, rabbits, and monkeys, half the animals were maintained in metabolism cages for 24 hours (Doweyko and Tortora, 1989). The amount of radioactivity in the feces, stomach and GI chyme were added together to estimate the amount of unabsorbed material. Rabbits had the highest amount of unabsorbed material (59.9%) relative to rats (43.7%) and monkeys (33.5%). The amount excreted in the urine was similar between these species, ranging from 7% (rabbits) to 11% (rats) of the applied dose. The amount excreted in the bile ranged from 0.1% (rabbits) to 8.2% (rats) of the applied dose. However, due to the short collection period and incomplete analysis of all tissues, the apparent recoveries in this study were relatively low, ranging from 50% in monkeys to 70% in rabbits.

In the pharmacokinetic study conducted by Gay (1994), the animals were maintained in metabolism cages for 48 hours while their bile and excreta were collected. Urine and feces were collected at 12, 24 and 48 hours. In both rats and mice, the majority of the radioactivity was found in the feces (approximately 64 and 45% of the applied dose, respectively), presumably as unabsorbed material. The percentage of the applied dose that was eliminated in the bile was similar for rats and mice (16 and 15%, respectively). Only 11 and 4% of the applied dose was excreted in the urine in rats and mice, respectively. Due to the short collection period and lack of tissue analysis, the recoveries in this study were usually less than 100%, especially for mice. For rats, the recoveries were relatively high, ranging from 88% in males to 99% in females. It is unclear if the lower recoveries in mice are due to a slower digestive tract (i.e., not all unabsorbed radioactive material in digestive tract excreted yet) or slower metabolism (i.e., not all absorbed radioactive material excreted yet).

B. ACUTE TOXICITY

Summary

Acceptable acute toxicity tests were available for not only the formulations, but also the technical grade propargite. The inhalation LC_{50} for technical grade propargite was 0.89 mg/L. Reddening of the lungs was observed macroscopically in some animals that died. Clinical signs

included labored breathing, anogenital stains, nasal discharge, moist rales, decreased activity and reduced body weights. The oral LD_{50} for technical grade propargite was 2800 mg/kg. Gastrointestinal abnormalities in most animals that died were considered to be due to the irritative properties of propargite. Other macroscopic findings in a few rats included dark red adrenal glands, bright red lungs and jaundice. Clinical signs included red and swollen paws, mouth and urogenital area, decreased urination and abnormal defecation. The dermal LD_{50} was greater than 4000 mg/kg, the only dose level tested. Severe dermal irritation was observed at this dose including erythema, edema, eschar, fissuring, desquamation, exfoliation and white-yellow exudate. Clinical signs included vocalization, abnormal defecation, inappetance, scabbing and swelling around the mouth, and staining around the nose and urogenital area. Technical grade propargite also caused severe eye irritation, but not dermal sensitization. The propargite emulsifiable concentrates were as toxic or more toxic than the technical grade material. Some formulations were corrosive to both the skin and eyes. The wettable powders were considerably less toxic than the technical grade material by the inhalation, oral and dermal route. Only slight dermal irritation was observed; however, the wettable powders were still corrosive to the eyes.

Technical Grade Propargite

The acute toxicity tests for technical grade propargite (90.3% purity) are summarized in Table 1. In the acute inhalation study, 5 Sprague-Dawley rats/sex/dose were exposed (nose-only) to aerosolized propargite (90.3% purity) for 4 hours at 0.31, 0.80 and 1.3 mg/L (analytical) (Hoffman, 1992a). The mass median aerodynamic diameter was 1.6 μm. Twenty-two percent of the particles were less than 1 μm and 100% were less than 10 μm. Therefore, the respiratory uptake was assumed to be 100%. One male died at 0.31 mg/L 4 days after exposure. One male and one female at 0.80 mg/L died two and three days after exposure, respectively. All the animals at 1.3 mg/L died between one and seventeen days after exposure. The most common clinical signs during exposure were labored breathing and anogenital staining. Decreased activity was also observed at 0.31 mg/L. Upon removal from the chambers, nasal discharge, matted coats and moist rales were seen in addition to the labored breathing and anogenital staining. Animals at 0.80 and 1.3 mg/L were held an additional 7 days to allow for recovery. Substantial reductions in body weights (5-30%) were observed at all dose levels in the first week after exposure. Reddening of the lungs was observed macroscopically in some of the animals that died and in some of the animals that were sacrificed. Other postmortem findings were sporadic and not considered treatment-related. The LC_{50} was 0.89 mg/L when both sexes were combined. The NOEL appears to be less than 0.31 mg/L based on the death, clinical signs, reduced body weights and discoloration of the lungs. This study was found acceptable to DPR based on the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) guidelines.

In the acute oral toxicity study, technical grade propargite (90.3% purity) was administered to 5 Crl:CD®BR rats/sex/dose at 2000, 2800 and 3920 mg/kg by oral gavage (Kiplinger, 1993a). Five and 10 animals died at 2800 and 3920 mg/kg. Clinical signs were seen at all dose levels and included swollen paws, red and swollen mouth and ears, swollen urogenital area in females, swollen penis and prepuce and necrotic areas on scrotum in males, abnormal defecation, decreased urination, hypoactivity, hypothermia, hypersensitivity to touch, rales, ataxia, dehydration, prostration, scabbing on ears, hair loss on base of tail and paws, dried or wet

Table 1. The Acute Toxicity of Technical Grade Propargite (90.3% purity)

Species	Sex	Results	References[a]
		Acute Inhalation LC_{50}	
Rat	M/F	0.89 mg/L (4-hour, nose-only)	1*
		Acute Oral LD_{50}	
Rat	M	2639 mg/kg	2*
	F	2947 mg/kg	
		Acute Dermal LD_{50}	
Rabbit	M/F	>4000 mg/kg	3*
		Primary Dermal Irritation	
Rabbit	M/F	Severe Irritation	4*
		Primary Eye Irritation	
Rabbit	M/F	Severe Irritation	5*
		Dermal Sensitization	
Guinea Pig	M/F	Non-sensitization	6

a References: 1. Hoffman, 1992a; 2. Kiplinger, 1993a; 3. Kiplinger, 1993b; 4. Kiplinger, 1993c; 5. Kiplinger, 1993d; 6. Kiplinger, 1993e.

* Study found acceptable based on FIFRA guidelines.

material on paws, mouth and eyes, and staining/discoloration of abdomen and urogenital area. Gross pathological examination found gastrointestinal abnormalities (stomach: dark red areas or foci, dark red contents and thickened mucosa; intestine: red fluid contents and distended) in most of the rats that died which were considered to be due to the irritative properties of the test article. Dark red or reddened adrenal glands were observed in 6 rats that died, which is a typical agonal or stress-related change. Five rats had bright red lungs and 3 rats were icteric (affected by jaundice). Other findings observed in only one rat included a reddened pituitary gland, a dark red prostate gland and dark red streaks on the urinary bladder. A thickened mucosa in the stomach was observed in two rats that survived. One male at 2800 mg/kg had small, soft testes. The oral LD_{50} was 2800 mg/kg when both sexes were combined. The NOEL appears to be less than 2000 mg/kg based on the clinical signs and external findings (scabbing, hair loss, matting, swelling) at necropsy. DPR found this study acceptable based on FIFRA guidelines.

In the acute dermal toxicity study, 5 New Zealand White rabbits/sex were administered technical grade propargite (90.3% purity) topically to their clipped backs (covered with gauze and secured with nonirritating tape) at 4000 mg/kg (Kiplinger, 1993b). Collars were used during the exposure period (24 hours) to prevent ingestion of the test compound. No deaths or changes in body weights were observed. Systemic effects were noted including vocalization, abnormal defecation, inappetance, scabbing and swelling around the mouth, and staining around the nose and urogenital area. Severe dermal irritation was seen including severe erythema and edema, eschar, white-yellow area in the application site, fissuring, desquamation, exfoliation and white-yellow exudate. Thickened skin and desquamation were noted at necropsy in all rabbits. One rabbit had reddened lungs. The dermal LD_{50} was greater than 4000 mg/kg, the only dose level tested. The NOEL was less than 4000 mg/kg based on the systemic effects and dermal irritation. This study was acceptable based on FIFRA guidelines.

In a dermal irritation study with 3 New Zealand White rabbits/sex, technical grade propargite (90.3% purity) caused severe dermal irritation including moderate erythema and edema, eschar, fissuring and desquamation (Kiplinger, 1993c). Slight erythema and edema and desquamation were still present at study termination. This study was acceptable to DPR based on FIFRA guidelines. Technical grade propargite (90.3% purity) caused severe eye irritation in 6 New Zealand White rabbits including mild corneal opacity and iritis that cleared by 10 days, discharge that cleared by 14 days and moderate redness and swelling of the conjunctiva that persisted through day 21 (Kiplinger, 1993d). DPR found this study acceptable based on FIFRA guidelines. The sensitization potential of technical grade propargite (90.3% purity) was tested in 6 Hartley guinea pigs/sex using a modified Buehler method (Kiplinger, 1993e). The animals were induced with a 0.1% solution and rechallenged with both a 0.1% and 0.2% solution. There was no reaction with either concentration that was attributed to sensitization, although the 0.2% solution caused slight irritation at the naive site.

Propargite Formulations

Acute toxicity studies for two propargite emulsifiable concentrates, Comite (73.6%) and Omite 6E (68.1%), are summarized in Table 2. Comite and Omite 6E were slightly more acutely toxic by the inhalation route compared to the technical grade material based on the LC_{50} values (Hoffman, 1992b&c). The clinical signs and macroscopic findings were similar to those seen with the technical grade material except that excessive salivation was also observed with both formulations. The acute oral toxicity of both emulsifiable concentrates were significantly more toxic than the technical grade material, presumably due to the inert ingredients in these formulations (Blaszcak, 1992a&b). Clinical signs observed after oral administration of these formulations included oral discharge or excessive salivation, watery or soft stool, urogenital staining, hypoactivity (Comite only), decreased food consumption and decreased fecal volume. Discoloration of the lungs and gastrointestinal tract was observed macroscopically after oral administration of both formulations. In addition, thickened stomach walls were seen with Comite. Omite 6E produced red nasal turbinates, fluid in the trachea and dark brown fluid in the urinary bladder in rats that died. The relative toxicity of the emulsifiable concentrates by the dermal route could not be compared with the technical grade material because only one dose level was tested with each of these formulations (Blaszcak, 1992c&d). Severe dermal irritation was observed with Omite 6E in the dermal toxicity study, but no systemic effects. Systemic effects were observed in the dermal toxicity study with Comite in part due to the higher dose level tested with Comite vs. Omite 6E (5000 mg/kg vs. 2000 mg/kg). The systemic effects included decreased food consumption and fecal volume, soft stools, fecal staining, hypothermia, nasal discharge, irregular breathing and emaciation. Comite also produced severe dermal irritation. In the dermal irritation studies, Comite and Omite 6E produced slight to moderate erythema and slight to moderate edema in the first 72 hours which progressed to necrosis and eschar formation with exfoliation (Blaszcak, 1992e&f). Comite produced severe eye irritation including severe conjunctival irritation, iridial damage, and corneal opacity, stippling and ulceration (Blaszcak, 1992g). Pannus and alopecia around the eye were observed at later intervals in the study. Ocular effects were still present at day 21. Eye irritation was also seen with Omite 6E, but it was less severe and had cleared by day 21 (Blaszcak, 1992h). Neither Comite or Omite 6E caused dermal sensitization (Blaszcak, 1992i&j).

Table 2. The Acute Toxicity of Propargite Emulsifiable Concentrates[a,b]

Species	Sex	Results	References[c]
		Acute Inhalation LC_{50}	
Rat	M/F	0.75 mg/L (4-hr, nose-only)[a]	1*
	M/F	0.83 mg/L (4-hr, nose-only)[b]	2*
		Acute Oral LD_{50}	
Rat	M/F	600 mg/kg[a]	3*
	M/F	593 mg/kg[b]	4*
		Acute Dermal LD_{50}	
Rabbit	M/F	>5000 mg/kg[a]	5*
		>2000 mg/kg[b]	6*
		Primary Dermal Irritation	
Rabbit	M/F	Corrosive[a]	7*
	M/F	Severe Irritation[b]	8*
		Primary Eye Irritation	
Rabbit	M/F	Corrosive[a]	9*
	M/F	Moderate Irritation[b]	10*
		Dermal Sensitization	
Guinea Pig	M/F	No sensitization[a]	11
	M/F	No sensitization[b]	12

a Comite (73.60% purity)
b Omite 6E (69.92% purity)
c References: 1. Hoffman, 1992b; 2. Hoffman, 1992c; 3. Blaszcak, 1992a; 4. Blaszcak, 1992b; 5. Blaszcak, 1992c; 6. Blaszcak, 1992d; 7. Blaszcak, 1992e; 8. Blaszcak, 1992f; 9. Blaszcak, 1992g; 10. Blaszcak, 1992h; 11. Blaszcak, 1992i; 12. Blaszcak, 1992j.
* Acceptable study based on the FIFRA guidelines

The acute toxicity tests for two propargite wettable powder formulations, Omite CR (30.02% purity) and Omite 30W (28.99% purity), are summarized in Table 3. The inhalation LC_{50} values of the wettable powders were significantly higher than the emulsifiable concentrates; however, the clinical signs observed were similar (Hoffman, 1993a & 1994a). The only macroscopic finding was thinning hair on the facial, ventral cervical/thoracic areas and forepaws which was observed with Omite CR, but not Omite 30W. The oral LD_{50} values for the wettable powders were also significantly higher than the emulsifiable concentrates. Clinical signs included anogenital staining, watery stool, ulcerations at the base of the tail, moist rales (Omite CR) and excessive salivation (Omite 30W). Red discoloration of lungs, fluid in the lungs and trachea (Omite 6E), urinary bladder distended with yellow fluid (Omite 6E) and intestine distended with gas (Omite 6E) were seen at necropsy in rats that died. Dilated renal pelvis, thickening of the stomach walls, white nodules on the spleen and enlarged lymph nodes were seen with Comite in rats that survived. The relative dermal toxicity of the wettable powders could not be compared with the emulsifiable concentrates or technical grade material since both formulations were only tested at 5000 mg/kg (Hoffman, 1993c & 1994c). No deaths or systemic effects were seen in these studies, only severe dermal irritation. Only slight erythema was observed in the dermal irritation studies for both wettable powders (Hoffman, 1993d & 1994d). On the other hand, both wettable powders were still corrosive with ocular effects still present on

Table 3. The Acute Toxicity of Propargite Wettable Powders[a,b]

Species	Sex	Results	References[c]
		Acute Inhalation LC_{50}	
Rat	M/F	> 6.4 mg/L (4-hour, nose-only)[a]	1*
	M/F	> 5.0 mg/L (4-hour, nose-only)[b]	2*
		Acute Oral LD_{50}	
Rat	M/F	> 5000 mg/kg[a]	3*
	M/F	>5200 mg/kg[b]	4*
		Acute Dermal LD_{50}	
Rabbit	M/F	> 5000 mg/kg[a]	5*
	M/F	> 5000 mg/kg[b]	6*
		Primary Dermal Irritation	
Rabbit	M/F	Slight Irritation[a]	7*
	M/F	Slight Irritation[b]	8*
		Primary Eye Irritation	
Rabbit	M/F	Corrosive[a]	9*
	M/F	Corrosive[b]	10
		Dermal Sensitization	
Guinea Pig	M/F	No Sensitization[a]	11

a Omite CR (30.02% purity)

b Omite 30W (28.99% purity)

c References: 1. Hoffman, 1993a; 2. Hoffman, 1994a; 3. Hoffman, 1993b; 4. Hoffman, 1994b; 5. Hoffman, 1993c; 6. Hoffman, 1994c; 7. Hoffman, 1993d; 8. Hoffman, 1994d; 9. Hoffman, 1993e; 10. Hoffman, 1994e; 11. Hoffman, 1993f.

* Acceptable study based on the FIFRA guidelines.

day 21 (Hoffman, 1993e & 1994e). Only results from a dermal sensitization test with Omite CR was available (Hoffman, 1993f). No evidence of dermal sensitization was found.

C. SUBCHRONIC TOXICITY

Summary

Two oral studies (rats and dogs) and two dermal studies (rabbits) were available for propargite. Only one of the dermal studies in rabbits was found acceptable based on FIFRA guidelines. The most common systemic effect with exposure to propargite, regardless of route, was reduced body weights. In addition, a slight increase in the incidence of several histopathological findings, including chronic nephritis, inflammation of the liver and hepatic necrosis, were seen in the 21-day dermal studies in rabbits. An increase in pigment in the reticuloendothelial cells of the liver and hemosiderosis of the spleen was observed in the dogs fed propargite for 13 weeks. Changes in hematological and clinical chemistry values were observed in another dermal study in rabbits. The lowest NOEL for systemic effects was 1 mg/kg/day based on the changes in hematological and clinical chemistry values. Dermal irritation was observed in both dermal studies. The NOEL for dermal irritation was less than 0.1 mg/kg/day.

Diet-Rat

Rats (number, sex and strain not reported) were fed technical grade propargite (purity not reported) in the diet at 10, 20, 40, 100 and 200 mg/kg/day for 90 days (Carson, 1964). No clinical signs were reported, although it is unclear if observations were made. Body weights and food consumption were reduced (percentage not reported) at 100 and 200 mg/kg/day. No abnormal hematological or clinical chemistry values were seen. No gross pathological lesions were found. Relative (to body), but not absolute weights of the liver, kidneys, adrenals and gonads were elevated in most groups probably due to body weight reductions. At 200 mg/kg/day major organs (not specified) were reduced in size. No microscopic lesions were found in the liver, kidneys, adrenals and gonads. The NOEL for this study appears to be 40 mg/kg/day. This study was unacceptable since only summary information was provided.

Diet-Dog

Three beagle dogs/sex/dose were fed technical grade propargite (purity not reported) in the diet at 2000 to 2500 ppm (dose intervals not specified) for 13 weeks (Hazleton, 1968). Three dogs/sex served as controls for this study and two other studies run simultaneously. The dogs had reduced food consumption and body weights. No effects were reported for clinical signs, hematology, clinical chemistry, organ weights or gross pathological lesions, except for a tendency for elevated serum glutamic-oxalacetic transaminase (SGOT or more currently referred to as aspartate aminotransferase or ASAT) activity and relative (to body) liver weight. An increase in pigment in the reticuloendothelial cells of the liver and hemosiderosis of the spleen were observed in the treated dogs. A NOEL could not be established due to insufficient information. This study was unacceptable since only summary information was provided.

Dermal-Rabbit

Technical grade propargite (purity not reported) was applied to the shaved backs of 5 HRA:(NZW)SPF rabbits/sex/dose at 0 (vehicle: acetone), 0.1, 1, 10 or 100 mg/kg/day for 6 hours/day, five days/week for 3 weeks (Bailey, 1987). One male rabbit at 100 mg/kg/day with an intussusception of the ileum into the cecum was sacrificed in a moribund condition. No treatment-related clinical signs were seen. Some signs of dermal irritation, such as erythema, thickening, epidermal scaling and fissuring were observed in all the dose groups, including the controls, which the investigators attributed to the vehicle (acetone). Atonia was observed in the skin in all treatment groups. More severe dermal effects were also observed at 10 mg/kg/day and higher including necrosis, sloughing and eschar. The mean body weights were significantly depressed at 10 mg/kg/day (F: 14-20%) and at 100 mg/kg/day (M: 12-16%; F: 14-18%) during the second and third weeks of the study (Table 4). There was no significant effect on food consumption. Increases in several hematological values were seen in one or both sexes at 10 and/or 100 mg/kg/day including white blood cell count, segmented neutrophils, monocytes and platelets. Changes in several clinical chemistry values were also seen in both sexes at 10 and 100 mg/day including a decrease in serum albumin and calcium and an increase in serum globulin. The veterinary pathologist for the study suggested that the hematological and clinical chemistry changes may be related to the dermal irritation. The decrease in albumin may be due to loss through exudate. The calcium may be reduced because it binds to albumin. The

Table 4. Possible Adverse Effects in Rabbits Treated Topically with Propargite for 21 Days[a]

Possible Adverse Effect		Dose Level (mg/kg/day)				
		0	0.1	1	10	100
Body weights wk 3 (kg)	M	2.61±0.15[b]	2.43±0.20	2.64±0.12	2.40±0.15	2.18±0.15*
	F	2.67±0.23	2.58±0.15	2.52±0.15	2.14±0.22*	2.20±0.20*
Platelets (1,000/µl)	M	352±53	435±73	559±158	687±203*	747±98*
	F	319±46	346±41	492±129	797±133*	949±186*
Neutrophils (1,000/µl)	M	1.8±1.0	1.9±0.6	3.2±1.0	4.3±1.9*	7.0±4.4*
	F	2.3±2.0	1.5±0.8	2.7±1.1	9.8±7.0*	7.7±3.8*
Monocytes (1,000/µl)	M	0.0±0.0	0.1±0.2	0.0±0.1	0.1±0.1	0.3±0.3
	F	0.0±0.0	0.0±0.1	0.0±0.0	0.3±0.3*	0.2±0.2*
Albumin (g/dl)	M	3.7±0.1	3.5±0.2	3.7±0.1	3.3±0.1*	3.2±0.2*
	F	3.7±0.1	3.6±0.1	3.6±0.1	3.3±0.2*	3.1±0.2*
Globulin (g/dl)	M	1.6±0.2	2.2±1.0	1.8±0.1	2.1±0.2*	1.9±0.2
	F	1.5±0.3	1.5±0.2	1.7±0.1	2.2±0.3*	2.0±0.3*
Calcium (mg/dl)	M	12.5±0.4	12.7±0.4	12.4±0.2	11.8±0.4*	11.6±0.7*
	F	12.1±0.2	12.3±0.5	12.4±0.2	11.8±0.4	11.9±0.5
Liver weights (% body)	M	2.03±0.11	2.05±0.17	2.08±0.11	2.18±0.26	2.52±0.17*
	F	2.04±0.23	1.96±0.17	2.07±0.22	2.53±0.28*	2.33±0.40
Kidney weights (% body)	M	0.58±0.05	0.83±0.55	0.60±0.03	0.67±0.06	0.72±0.08*
	F	0.58±0.07	0.57±0.03	0.63±0.04	0.73±0.10*	0.67±0.03
Hepatic necrosis	M	0/5	0/5	0/5	0/5	1/5
	F	0/5	0/5	0/5	0/5	1/5
Acanthosis	M	0/5	5/5*	5/5*	5/5*	4/5*
	F	0/5	4/5*	5/5*	5/5*	5/5*
Hyperkeratosis	M	0/5	4/5*	4/5*	4/5*	4/5*
	F	0/5	0/5	4/5*	5/5*	5/5*
Subepidermal infiltrate	M	0/5	5/5*	5/5*	5/5*	5/5*
	F	0/5	5/5*	3/5	4/5*	5/5*
Skin, edema	M	0/5	0/5	1/5	3/5	4/5*
	F	0/5	0/5	2/5	2/5	5/5*
Skin, necrosis	M	0/5	2/5	1/5	1/5	2/5
	F	0/5	0/5	2/5	0/5	1/5

a Bailey, 1987.
b Mean ± standard deviation.
* Significantly different from controls, $p \leq 0.05$.

increased globulin may be due to increased immunoglobulins. An increase in relative (to body) liver and kidney weights was seen at 10 mg/kg/day (F: 24% and 26%, respectively) and 100 mg/kg/day (liver - M: 24%, F: 14%; kidney - M: 24%, F: 16%). The investigator suggested these relative organ weight changes may be related to reduced body weight changes; however, the histopathological lesions in the liver and kidney at 100 mg/kg/day in this study and the other 21-day dermal study conducted by Goldenthal (1989) suggest they may be related to organ toxicity. The only gross pathological lesions observed at necropsy were the same dermal effects that were seen clinically. Histopathological examination revealed focal hepatic necrosis in one male and one female at 100 mg/kg/day. Dermal microscopic findings in untreated and/or treated skin included acanthosis, hyperkeratosis, subepidermal inflammatory infiltrate, necrosis, erosion/ulceration, subepidermal edema and hemorrhage at 0.1 mg/kg/day or higher. The severity of these dermal lesions increased with dosage with the dermal lesions being minimal to slight at 0.1 mg/kg/day, slight to moderate at 1 mg/kg/day, moderate at 10 mg/kg/day and moderate to moderately severe at 100 mg/kg/day. Erosion and ulceration were only observed at 100 mg/kg/day. The acanthosis resulted in papillary projections into the epidermis in some rabbits at 10 and 100 mg/kg/day, but the incidence was not dose-related. The NOEL for systemic effects was 1 mg/kg/day based on reduced body weights, changes in clinical chemistry and hematology values and increases in relative liver and kidney weights. The NOEL for dermal irritation was less than 0.1 mg/kg/day based on clinical signs (very slight to well-defined erythema, thickening, epidermal scaling, fissuring and atonia) and microscopic lesions (acanthosis, hyperkeratosis, subepidermal inflammatory infiltrate and necrosis). DPR found this study acceptable based on FIFRA guidelines.

Dermal-Rabbit

Groups of 5 New Zealand White rabbits/sex/dose had technical grade propargite (86.6% purity) applied to their shaved backs at 0, 0.1, 1.0, 10 and 100 mg/kg (0, 2.1, 4.5, 12.5 or 28 mg/cm^2) for 5 days/week for 3 weeks (Goldenthal, 1989). There was no treatment-related effect on mortality or clinical signs. Marked dermal irritation in the form of erythema, edema, eschar, exfoliation, atonia, desquamation, fissuring, blanching and/or coriaceousness (leatheriness) was observed at all dose levels with dose-related increases in severity and incidence. The onset was earlier at the higher dose levels. Treated males tended to have slightly lower mean body weights than controls; however, the differences were not statistically significant. Both sexes tended to have slightly lower mean food consumption in all the treatment groups, but the differences were only statistically significant for females at 0.1, 1.0 and 10 mg/kg/day in week 2 of the study and at 100 mg/kg/day in week 1 of the study. At necropsy, a statistically significant increase in segmented neutrophils was observed in males at 100 mg/kg/day. The investigator did not consider this finding biologically significant since it was an isolated finding; however, increased neutrophils were also observed in the 21-day dermal study conducted by Bailey (1987) who suggested it may be related to the dermal irritation. There were no other significant hematological or biochemical changes in the blood. Microscopic lesions were observed in the treated skin at all dose levels, including acanthosis, hyperkeratosis, inflammation, necrosis and abscess. The dermal inflammation did not show a dose-related trend in the incidence and severity, unlike acanthosis and hyperkeratosis. An increase in chronic interstitial nephritis (0: 2/10 vs. 100: 5/10) and inflammation of the liver (0: 2/10 vs. 100: 4/10) was observed in both sexes at 100 mg/kg. Mild hepatic necrosis was also observed in 2 females at 100 mg/kg. The NOEL for these lesions was uncertain since the kidney and liver were not examined

microscopically at 0.1, 1 or 10 mg/kg/day. The NOEL for dermal irritation was less than 0.1 mg/kg/day based on clinical signs (erythema, edema, eschar, exfoliation, atonia, desquamation, fissuring, blanching, coriaceousness) and microscopic lesions (acanthosis, hyperkeratosis, inflammation). This study was unacceptable to DPR toxicologists, but ungradable with submission of histopathology data on the intermediate treatment groups.

D. CHRONIC TOXICITY/ONCOGENICITY

Summary

One mouse, two rat and two dog studies were available for propargite. All five studies were oral studies. Only the mouse, one rat and one dog study were found acceptable based on FIFRA guidelines. Reduced body weights and food consumption were the most prevalent effects observed. Reduced survival was observed in both rat studies. Changes in hematological values were seen in both rats and dogs. Changes in clinical chemistry values were also seen in rats. Most of these changes were of uncertain toxicological significance. Changes in organ weights (usually increases in relative and decreases in absolute), seen in several studies, were probably related to body weight reductions. An increase in sarcomas of the jejunum was observed in Sprague-Dawley rats, but not Wistar rats or mice. Several supplemental studies were conducted to ascertain the mechanism for tumor formation. The stabilizer, propylene oxide, does not appear to be responsible. One study suggests that increased cell proliferation may be the mechanism for the tumor formation. Microscopic lesions in the lungs (congestion or inflammation), thymus (involution) and bone marrow (atrophy) were seen in one dog study at 1250 ppm and higher. The lowest NOEL in the chronic studies appears to be 80 ppm (M: 3.8 mg/kg/day: F: 4.7 mg/kg/day) based on slight reductions in body weights and food consumption in rats.

Diet-Mouse

Groups of 60 CD-1 mice/sex/dose were administered propargite (purity 84.3 - 88.5%) in the diet at 0, 50, 160, 500 or 1000 ppm (0, 24, 75 or 150 mg/kg/day[1]) for 18 months (Block I) (Cox and Re, 1979). An additional 15 mice/sex/dose were fed propargite at 0, 500 or 1000 ppm for 12 months (Block II). There was no effect on survival except for a greater survival of Block I males at 160, 500 and 1000 ppm during the first 12 months. There was no effect on clinical signs, body weights, food consumption and hematology. Changes in some absolute (A) or relative (R) organ weights were observed in the kidney (160 ppm - M: R ↓11%; 1000 ppm - F: A ↓11%) and uterus (160 ppm - F: R ↑53%; 1000 ppm - F: A ↑75%, R ↑84%) in Block I animals. Increased organ weights were also seen in the kidney (1000 ppm - M: R 10%), adrenal (500 ppm - F: A 50%, R 46%; 1000 ppm - F: A 46%, R 46%) and thyroid (500 ppm - F: A 60%, R 64%) in Block II animals. Microscopic examination revealed no treatment-related pathologic lesions in these organs; therefore, the toxicological significance of these findings is uncertain. There was no treatment-related increase in neoplasms. The NOEL for this study is equal to or greater than 1000 ppm, the highest dose tested (HDT). DPR toxicologists initially found this study

[1] Estimated assuming for a mouse that 1 ppm in the diet is equivalent to 0.150 mg/kg/day (FDA, 1959).

unacceptable due to the lack of effects at the HDT; however, after submission of additional data (test article characterization, homogeneity and stability and U.S. EPA's review of this study), this study was upgraded to acceptable.

Diet-Rat

In a combined chronic toxicity/reproductive toxicity study, 37 (controls) or 25 (treated) FDRL (Wistar-derived) rats/sex/dose were fed propargite (purity not reported) in the diet at 0, 100, 300, or 900 ppm (nominal compound intake: 0, 5, 15 or 45 mg/kg/day) for 2 years (FDRL, 1966). After 6 months, two more groups were added which were fed propargite at 0 (15 rats/sex) or 2000 ppm (25 rats/sex; nominal compound intake: 100 mg/kg/day) for 1.5 years. To avoid excessive dosages in the weanlings, the dietary concentrations were increased biweekly during the first 10 weeks of exposure starting at 42, 125, 380 and 833 ppm to reach the adult levels of 100, 300, 900 and 2000 ppm. When rats were 100 days old, 20 pairs of male and female rats from the control and 100 ppm groups were mated. At weaning, 10 pups/sex from the second litters were designated as the F_1 generation and maintained on the same diet as their parents for 12 weeks. The F_2 pups were then mated as above. At weaning, the dose level for F_2 pups was increased to 300 ppm. The F_3 generation reached maturity about the same time the 2-year test period of the F_0 generation was terminated. There was no effect on reproductive performance or survival and growth of offspring. In the chronic toxicity study, the survival of males at 2000 ppm was lower than controls at 18 months (68% vs. 93%). There was no significant effect on body weights and food consumption at 100, 300 and 900 ppm. Significantly lower body weight gains and cumulative food consumption were seen in males (30% and 10%, respectively) and females (34% and 25%, respectively) at 2000 ppm at termination. There was no effect on hematology, clinical chemistry or urinalysis including the descendent generations. Initial review of the gross and histopathological findings suggested there were no treatment-related effects. After reviewing the chronic toxicity/oncogenicity study conducted by Trutter (1991), the pathological findings in this study were reevaluated. The pathology findings were difficult to interpret since the cell type or organ of origin or other details were often missing. Although not definitive, there was an apparent dose-related increase in sarcomas of the intestine with characteristics resembling the undifferentiated sarcomas observed in the jejunum of rats in the Trutter (1991) study. These sarcomas included spindle cell sarcomas, myosarcomas and osseous sarcomas. These sarcomas were seen in 1 male at 300 ppm, 3 males and 1 female at 900 ppm and 3 males and 1 female at 2000 ppm. A NOEL was not clearly established in this study due to insufficient information, but appears to be 900 ppm (45 mg/kg/day) based on the reduced survival, body weight gains and cumulative food consumption at 2000 ppm (100 mg/kg/day). This study was unacceptable to DPR due to major deficiencies including an inadequate number of animals per group, incomplete histopathological examination and no analysis of the diets.

Diet-Rat

Technical grade propargite (87.2% purity) was fed to 60 Crl:CD®BR rats/sex/dose in the diet at 0, 50, 80, 400 or 800 ppm (M: 0, 2.4, 3.8, 19.2 or 38.9 mg/kg/day; F: 0, 2.9, 4.7, 23.6 or 49.4 mg/kg/day) for 103 weeks (males) or 104 weeks (females) (Trutter, 1991). Ten rats/sex/dose were sacrificed at week 53. There was a reduction in survival of males at 400 and 800 ppm with a positive linear trend in mortality for the male test groups. However, mortality rates were not significantly different between the control and test groups for either sex, except

for a significantly lower mortality rate for males at 50 ppm. Reduced body weights were observed in both sexes at 400 ppm (M: 4-6%; F: 2-4%) and 800 ppm (M: 12-17%; F: 10-20%), although females at 400 ppm recovered over time (Table 5). A reduction in food consumption was also observed at 400 ppm (M: 2-5%; F: 2-4%) and 800 ppm (M: 12-17%; F: 12-13%). There were no treatment-related differences in clinical signs, ophthalmologic findings or urinalysis. There was a significant increase in reticulocyte counts in males at 800 ppm that was associated with non-significant decreases in erythrocyte counts, hemoglobin and hematocrit values and an increase in nucleated erythrocyte count. A significant increase in platelet counts was also seen in females at 800 ppm at weeks 26 and 52, but it is of uncertain toxicological significance. A significant decrease in glucose level was observed in females at 800 ppm at week 78. Total protein and calcium values were significantly lower in males at 400 and 800 ppm and in females at 800 ppm at week 26. The reduction in calcium levels may be related to the reduction in protein levels since a large portion of the calcium is protein-bound. Significant decreases in globulin and increased albumin to globulin ratios were also seen at week 26 in males at 800 ppm. Non-significant decreases in total protein and globulin persisted until the study termination in males at 800 ppm. Significant reductions in aspartate aminotransferase (ASAT) and alanine aminotransferase (ALAT) activities were seen in females at 400 and 800 ppm. The reductions in glucose, total protein, globulin, ASAT and ALAT levels may be related to the decreased food consumption. Significant increases in relative (to body) organ weights were seen at week 53 for the liver at 400 and 800 ppm (F: 17% and 38%, respectively) and for the kidney (M: 12%, F: 35%) and brain (M: 12%, F: 33%) at 800 ppm. These increases may be related to the body weight reductions. Many of the unscheduled deaths after week 65 at 800 ppm were in animals with abdominal masses which were associated with the small intestine. Histopathological examination revealed that these masses were undifferentiated sarcomas in the jejunum (Table 6). The increases in this rare tumor were statistically significant by pairwise comparison with controls in males at 400 ppm and in both sexes at 800 ppm. There was also a significant positive trend for these tumors in both sexes. Ulceration and ectatic mucosal glands at the tumor site were often associated with these tumors. No other treatment-related increases in histopathological lesions were seen. The NOEL for this study was 80 ppm (M: 3.8 mg/kg/day; F: 4.7 mg/kg/day) based on the slight reductions in body weights and food consumption. DPR found this study acceptable based on the FIFRA guidelines.

The registrant had a consultant pathologist, Dr. R.A. Squire, analyze the data from the Trutter study (1991) in an attempt to determine the cause of the unanticipated increase in undifferentiated sarcomas (Cardona et al., 1991). He agreed with the original diagnosis as undifferentiated sarcomas. He proposed that the propylene oxide stabilizer in the technical grade material may be responsible since it is genotoxic. He also suggested that propargite is ulcerogenic at the doses that are carcinogenic, allowing lumenal exposure of the submucosal mesenchymal cells. Examination of the tumors revealed that most were ulcerated, suggesting that epithelial erosion and ulceration may have preceded and been required for tumor formation. To further evaluate the possible role of ulceration in the development of these tumors, Dr. Squire examined 10 additional jejunal step sections in 26 males that did not have tumors at 0 and 800 ppm. Among the males at 800 ppm, 5 had focal epithelial necrosis and 2 of these were large ulcers with submucosal stromal and inflammatory responses. The smallest lesions were crypt abscesses filled with necrotic cell debris and surrounded by attenuated epithelium, portions of which were necrotic. No crypt abscesses, ulcers, epithelial necrosis or other similar lesions were found in the control animals.

Table 5. Possible Adverse Effects in Rats Fed Propargite in the Diet for 104 Weeks[a]

Possible Adverse Effect		Dose Level (ppm)				
		0	50	80	400	800
Body wt. change wks 0-24 (g)	M	422±78[bT]	424±75	402±90	372±102*	346±53*
	F	279±101[T]	291±90	303±108	280±76	237±52
Total food cons. wks 0-24 (g)	M	3331±298[T]	3336±272	3301±262	3156±249*	2773±171*
	F	2467±205[T]	2495±218	2459±228	2375±167*	2136±156*
Reticulocytes wk 104 (10^6/µl)	M	0.25±0.16	-----	-----	0.25±0.18	0.54±0.25*
	F	0.13±0.12	-----	-----	-----	0.16±0.12
Platelets wk 52 (10^3/µl)	M	1305±114[M]	1256±154	1392±176	1367±151	1320±190
	F	1129±136[M]	1176±120	1152±110	1196±182	1350±136*
Glucose wk 78 (mg/dl)	M	112±13	111±13	112±14	113±13	106±19
	F	110±20[T]	106±15	100±16	99±16	83±16*
Total protein wk 26 (g/dl)	M	7.3±0.3[T]	7.1±0.4	7.5±0.3	7.0±0.4*	6.7±0.3*
	F	8.1±0.4	7.6±0.5	7.8±0.6	8.2±0.6	7.4±0.4
Globulin wk 26 (g/dl)	M	2.6±0.2[T]	2.5±0.4	2.8±0.4	2.5±0.3	2.1±0.3*
	F	2.1±0.2[M]	2.1±0.3	2.1±0.2	2.1±0.4	2.0±0.3
Calcium wk 26 (mg/dl)	M	10.3±0.3[T]	10.1±0.2	10.4±0.4	10.0±0.3*	10.0±0.3*
	F	10.9±0.3	10.8±0.6	10.6±0.5	10.9±0.4	10.3±0.3*
ASAT wk 26 (U/l)	M	132±34[T]	136±48	116±29	118±30	99±18
	F	214±154[T]	117±25*	171±109	112±38*	106±32*
ALAT wk 26 (U/l)	M	42±7[T]	48±16	42±15	38±16	34±5
	F	105±105[M]	40±10*	89±110	38±9*	38±17*
Liver wt. wk 53 (% body)	M	2.64±0.38[M]	2.69±0.83	2.54±0.27	2.65±0.32	2.94±0.38
	F	2.43±0.17[T]	2.62±0.14*	2.79±0.66	2.83±0.32*	3.35±0.32*
Kidney wt. wk 53 (% body)	M	0.63±0.07	0.62±0.08	0.62±0.05	0.65±0.07	0.71±0.06*
	F	0.59±0.06[T]	0.65±0.08	0.71±0.18*	0.66±0.11	0.79±0.08*
Brain wt wk 53 (% body)	M	0.36±0.04	0.34±0.03	0.36±0.03	0.36±0.03	0.41±0.04*
	F	0.50±0.05[T]	0.53±0.09	0.53±0.10	0.55±0.08	0.66±0.07*

a Trutter, 1991.
b Mean ± standard deviation.
T Significant trend, $p \leq 0.05$.
* Significantly different from controls, $p \leq 0.05$.
M Significant monotonic trend, $p \leq 0.05$.

Table 6. Histopathological Lesions in Jejunum of Rats Fed Propargite in the Diet for 104 Weeks[a]

Lesion	Dose Level (ppm)				
	0	50	80	400	800
MALES					
Sarcoma	0/44[b+++] (0%)	0/47 (0%)	0/44 (0%)	11/46*** (24%)	24/46*** (52%)
Ulceration, tumor site	0/49[c+++] (0%)	0/47 (0%)	0/46 (0%)	3/49 (6%)	10/50*** (20%)
Ectatic mucosal glands, tumor site	0/49[c+++] (0%)	0/47 (0%)	0/46 (0%)	3/49 (6%)	6/50* (12%)
FEMALES					
Sarcoma	0/45[b+++] (0%)	1/49 (2%)	1/49 (2%)	1/47 (2%)	12/45*** (27%)
Ulceration, tumor site	0/47[c++] (0%)	1/49 (2%)	0/49 (0%)	0/47 (0%)	3/47 (6%)
Ectatic mucosal glands, tumor site	0/47[c+] (0%)	1/49 (2%)	0/49 (0%)	0/47 (0%)	2/47 (4%)

a Trutter, 1991.
b The denominator is the number of animals at risk (excluding those that died before week 52); the first tumor observed week 65; the number in the parentheses represents the incidence in percentage.
c The denominator is the number examined.
+, ++, +++ Significant trend based on the Cochran-Armitage trend test at $p < 0.05$, 0.01 and 0.001, respectively.
*, *** Significantly different from controls based on the Fisher's exact test at $p < 0.05$ and 0.001, respectively.

To address the possible role of the stabilizer, propylene oxide, in the oncogenic response in the Trutter (1991) study, a new oncogenicity study was conducted with a reformulated technical grade propargite that contained epoxidized soybean oil as the stabilizer. Sixty male CD® rats /dose were fed the reformulated technical grade propargite (89.1% purity) in the diet at 0 or 800 ppm (0 or 36.3 mg/kg/day) for 2 years (Goldenthal, 1993). Ten rats/dose were sacrificed at 1 year. There was an increase in mortality in the treated males in the second year. No treatment-related clinical signs were observed. There was a significant reduction in food consumption (up to 23%) and body weights (up to 18%) in treated males. Increases in relative (to body) organ weights were seen in the brain, kidney, liver and testis that were probably related to the decreased body weights. Macroscopic and microscopic examination of the animals revealed an increase in undifferentiated sarcomas in the duodenum (2/47), jejunum (23/47) and soft tissue of the abdomen (1/1) of treated animals relative to controls (duodenum: 0/50; jejunum: 0/49; soft tissue, abdomen: 0/0). Most of the treated rats that died or were killed in a moribund condition on the study had undifferentiated sarcomas (19/28) compared to the survivors (4/17). This study indicates that the propargite itself, not the stabilizer, is responsible for the oncogenic response. This supplemental study was not intended to be a FIFRA guideline study and did not have enough dose levels to establish a NOEL.

To evaluate the possible role that necrosis and ulceration had in the oncogenic response in the Trutter (1991) study, a cell proliferation study was conducted (Eldridge, 1994). Technical grade propargite (88.64% purity) was administered in the diet to male CD rats at 0, 80 or 800 ppm, female CD rats at 0, 40 or 800 ppm and male CD-1 mice at 0 or1000 ppm up to 4 weeks. Twelve and 22 animals/sex were assigned to each of the control and treatment groups, respectively. At 1 and 4 weeks, half the animals were sacrificed and sections of the jejunum were collected for cell proliferation analysis. Three different smooth muscle layers were evaluated: the muscularis mucosa, and both the inner circular layer and the outer longitudinal layer of smooth muscle from the tunica muscularis. One week prior to sacrifice, osmotic pumps containing 5-bromo-2'-deoxyuridine (BrdU) were placed under the skin of the rats. Cells that incorporated BrdU were identified by staining of their nuclei. Cell proliferation was expressed as a unit length labeling index (ULLI; number of labeled cells per mm). The total ULLI for all three smooth muscle layers was significantly elevated (3-4 fold over controls) in both sexes at 800 ppm at week 1. The increase in the total ULLI was also statistically significant in males at 800 ppm at week 4; however, the investigators did not consider this increase biologically significant since the increase was less than two-fold over controls. There was no significant increase in the total ULLI in the male rats at 80 ppm, female rats at 40 ppm or male mice at 1000 ppm at either week 1 or week 4. The investigator noted that although the increase in cell proliferation was transient, that a transient increase in cell proliferation has been observed with mitogenic nongenotoxic carcinogens (Eldridge *et al.* 1992; Tilbury *et al.*, 1993). Furthermore, a NOEL was established for cell proliferation in this study at 80 ppm (4 mg/kg/day) in male rats and 40 ppm (2 mg/kg/day) in female rats. This was not a guideline study, but was conducted according to Good Laboratory Practice (GLP) regulations and provided useful information regarding the possible mechanism of action for the oncogenicity.

In order to understand the apparent lack of an oncogenic response in the Wistar rat, a second cell proliferation study was conducted in which Wistar (WKY) rats were fed technical grade propargite (88.64% purity) for 1 week at 0 ppm (6 rats/sex) or 900 ppm (11 rats/sex) (Eldridge, 1995). As before, osmotic pumps containing BrdU were implanted under the skin in the rats one week before the animals were sacrificed. The same three layers of smooth muscle from the jejunum were examined for cell proliferation. There was a statistically significant increase (200%) in the outer longitudinal layer of the tunica muscularis in females at 900 ppm, but the investigator did not think this was biologically meaningful since cell proliferation in the total smooth muscle was not significantly increased. The investigators suggested that this study may explain the apparent negative response in the FDRL (1966) study in Wistar rats.

Diet-Dog

Eight beagle dogs/sex/dose were fed propargite (purity not reported) in the diet at 0, 100, 300 or 900 ppm (0, 2.5, 7.5 or 22.5 mg/kg/day)[2] for 2 years (FDRL, 1966). At one year one dog/sex/dose was sacrificed and was examined for gross pathological lesions. Two dogs (1 male at 100 ppm and 1 female at 300 ppm) died from causes unrelated to treatment. There was no effect on body weights, food consumption, hematology, clinical chemistry, urinalysis, or gross or histopathological findings. The NOEL appears to be 900 ppm. This study was unacceptable to

[2] Estimated assuming for a dog that 1 ppm in the diet is equivalent to 0.025 mg/kg/day (FDA, 1959).

DPR due to major deficiencies including no analysis of the diet, inadequate pathological examination and no evidence of toxicity at the highest dose level.

Diet-Dog

Omite technical (88.6% purity) was fed to 6 beagle dogs/sex/group in the diet at 0, 160, 1250 and 2500 ppm (4, 31 and 62 mg/kg/day)[2] for 1 year (Atkinson, 1991). At day 57 (week 8), the high-dose level was decreased to 1875 ppm (47 mg/kg/day) due to excessive body weight losses. At 1875 ppm, one male and one female were sacrificed in moribund condition. Both animals had marked body weight losses which were considered treatment-related. Moderate to marked decreases in body weights were observed at 1250 ppm (M: 18%, F: 20%) and 1875 ppm (M: 58%, F: 50%). Food consumption was reduced during weeks 1-8 when the high dose was 2500 ppm (M: 42-60%, F: 43-67%). After the high dose was reduced to 1875 ppm, the food consumption was still reduced (M: 9-25%, F: 1-20%), but the difference was no longer statistically significant except for females at week 9. The investigator suggested that palatability of the high-dose diet may have been a factor in the reduced food consumption. The investigator attributed the decreased body weights to the decreased food consumption; however, this does not explain the body weight reduction at 1250 ppm since there was no reduced food consumption at this dose level. Significant reductions in several hematological parameters were observed at 1250 and 1875 ppm, including RBC counts, hematocrit and hemoglobin values. A significant increase in platelet counts was also observed at 1250 and 1875 ppm. Increases in various relative organ weights (to body weight) were observed primarily at 1875 ppm (adrenal glands - M: 55%, F: 53%; liver - M: 53%, F: 35%; kidney - F: 31%; testes - M: 68%; thyroid/ parathyroid - M: 53%, F: 44%), but occasionally at 1250 ppm (liver - M: 38%, F: 28%). The absolute organ weights were decreased at 1875 ppm for several organs (heart - M: 39%, F: 40%; kidney - M: 34%, F: 33%; ovaries - F: 52%). Both the increased relative organ weights and the decreased absolute organ weights were attributed to reduced body weights by the investigator. Microscopic lesions in the stomach (vacuoles in parietal cells), thymus (involution) and bone marrow (erythroid/myeloid depletion/atrophy) were observed at 1250 ppm (stomach - M: 6/6, F: 4/6; thymus - F: 5/6) and 1875 ppm (stomach - M: 6/6, F: 5/6; thymus - M: 6/6, F: 4/5; bone marrow - M: 6/6, F: 5/6). Microscopic lesions in the lungs (foci of congestion or serosal subacute/chronic inflammation) were also observed in females at 160 and 1275 ppm, but not at 1875 ppm and, therefore, were not considered treatment related. The NOEL was 160 ppm (4 mg/kg/day) based on reduced body weights, hematological changes, increased relative liver weights and involution of the thymus. DPR toxicologists found this study acceptable based on FIFRA guidelines.

E. GENOTOXICITY

Summary

There was no evidence of an increase in gene mutation in reverse mutation assays with *Salmonella typhimurium* (strains TA1535, TA1537, TA1538, TA98 and TA100), *Saccharomyces cerevisiae* (D4 strain) and *Escherichia coli* (WP2 *hcr* strain). None of these assays were found acceptable by DPR toxicologists. A significant increase in mutation frequency was observed in a marginally acceptable forward mutation assay with Chinese

hamster ovary (CHO) cells that measured mutations in the hypoxanthine-guanine phosphoribosyl transferase (HPRT) locus. However, analysis of the dosing solutions revealed that the propargite had either broken down or reacted with the vehicle, DMSO. More recent, well-conducted studies with acetone or DMSO as the vehicle at similar concentrations were negative. No evidence of chromosomal aberrations was found in an *in vitro* cytogenetics assay with CHO cells and an *in vivo* micronucleus cytogenetics assay in mice. Both of these tests were acceptable. A rec assay with *Bacillus subtilis* H17 (rec^+) and M45 (rec^-) strains and an unscheduled DNA synthesis (UDS) assay with rat primary hepatocytes were also negative. The rec assay was not acceptable to DPR toxicologists, but the UDS assay was acceptable. Based on these studies, it appears that the genotoxic potential of propargite in humans is low.

Gene Mutation

In a reverse mutation assay, *Salmonella typhimurium* (strains TA1535, TA1537, TA1538, TA98 and TA100) was exposed to propargite (purity 91%) at 0, 0.001, 0.01, 0.1, 1.0 or 5.0 µl/plate with and without metabolic (S-9) activation (Brusick, 1977). Brusick also exposed *Saccharomyces cerevisiae* D4 strain to the same concentrations of propargite. There was no increase in mutation frequency with any strain at any concentration. DPR toxicologists found this study unacceptable due to multiple deficiencies. In another reverse mutation assay, propargite (purity 90.9%) was tested with *S. typhimurium* strains TA1535, TA1537, TA1538, TA100 and TA98 and *Escherichia coli* strain WP2 *hcr* at 0, 10, 50, 100, 500, 1000 or 5000 µg/plate with and without S-9 (Shirasu *et al.*, 1979). No increase in mutation frequency was observed with any strain at any concentration. This study was also unacceptable to DPR toxicologists due to insufficient replicates and questionable culture characteristics.

Three forward mutation assays with Chinese hamster ovary (CHO) cells that measured mutations at the hypoxanthine-guanine phosphoribosyl transferase (HPRT) locus were submitted to DPR by the registrant. In the first assay submitted, technical grade propargite (purity not stated) was tested at 0.01 to 15 µg/ml with and without S-9 using DMSO as the vehicle (Godek, 1987). Concentrations of 1.0 µg/ml or greater without S-9 resulted in reduced cell survival. At 0.05 to 0.75 µg/ml statistically significant increases in the mutation frequency were observed. Analysis of the dosing solutions revealed that propargite had either broken down or reacted with the DMSO. Therefore, propargite was tested again at 0.005 to 1.0 µg/ml without S-9 and 0.75 to 15 µg/ml with S-9 using acetone as the vehicle. There was no increase in mutation frequency with or without S-9. DPR toxicologists considered this study marginally acceptable with a possible genotoxic effect without activation. The registrant submitted two more assays, one with acetone as the vehicle and the other with DMSO as the vehicle. In the assay with acetone as the vehicle, propargite technical (90% purity) was tested at 0.5 to 5 µg/ml without S-9 and at 5 to 50 µg/ml with S-9 (Bigger and Clarke, 1993a). No increase in mutation frequency was observed with or without S-9. DPR toxicologists found this study acceptable based on the guidelines. In the assay with DMSO as the vehicle, propargite technical (90% purity) was tested at 0.2 to 5 µg/ml without S-9 and at 10 to 75 µg/ml with S-9 (Bigger and Clarke, 1993b). No concentration related increase in mutation frequency was seen with or without S-9 in this study. This study was also found acceptable by DPR toxicologists based on the guidelines.

Chromosomal Aberrations

An *in vitro* cytogenetics assay was conducted using cultured Chinese hamster ovary (CHO) cells with propargite (purity not stated) at 25 to 100 μg/ml without S-9 and 25 to 200 μg/ml with S-9 (Kirkland, 1985). No increase in chromosomal aberrations was observed when tested up to the limits of cytotoxicity. DPR toxicologists found this study acceptable. In a micronucleus cytogenetic assay, ICR mice were given a single intraperitoneal injection of propargite (89.56% purity) at 0 (corn oil), 37.5, 75, or 150 mg/kg (Putman and Young, 1994). Five mice/sex/dose were sacrificed at 24, 48 and 72 hours. The proportion of polychromatic erythrocytes to total erythrocytes was reduced in male and female mice at 75 and 150 mg/kg at 48 and 74 hours after treatment; however, there was no increase in micronucleated erythrocytes. This study was found acceptable by DPR toxicologists based on the FIFRA guidelines.

Other Genotoxic Effects

Shirasu *et al.* (1979) also conducted a rec-assay in which *Bacillus subtilis* H17 (rec^+) and M45 (rec^-) strains were exposed to propargite (90.9% purity) at 1 to 100% (v/v in DMSO). Propargite did not induce any inhibitory zone around either strain at all doses tested. DPR toxicologists found this study unacceptable since there were no replicates or repeats. In an unscheduled DNA synthesis (UDS) assay, rat primary hepatocytes were exposed to technical grade propargite (purity not stated) at 0.0167 to 5000 μg/ml for 18-20 hrs in triplicates (Barfknecht, 1987). UDS was quantified by autoradiography using ^{3}H-thymidine in 50 nuclei per slide. No evidence of treatment-related UDS was observed. This study was found acceptable by DPR toxicologists.

F. REPRODUCTIVE TOXICITY

Summary

Two reproductive toxicity studies in rats were available for propargite, the main study and an ancillary cross-fostering study. The main study was found acceptable based on FIFRA guidelines. The primary effect observed in the main study was a reduction in the body weights of both the adults and pups. Propargite had no effect on mating, fertility or gestation. There was also no treatment-related effect on macroscopic and microscopic lesions. The NOEL was 80 ppm (4 mg/kg/day) for both reproductive effects (reduced pup weights) and parental effects (reduced parental weights). The cross-fostering study was conducted to determine if the pup weight reduction was due to maternal toxicity or direct consumption of propargite in breast milk or the diet. The investigators suggested that the weight reductions are due to direct consumption of propargite in the diet by the pups since they were not observed until the latter half of the lactation period, but DPR toxicologists concluded that dam-mediated effects could not be ruled out.

Diet-Rat

Propargite (87.2% purity) was administered to 25 Crl:CD BR (Sprague-Dawley) rats/sex/dose at 0 (corn oil and chow), 80, 400 or 800 ppm (0, 4, 20 or 40 mg/kg/day)[3] for two generations with 2 litters per generation (Kehoe, 1990). Body weights were significantly lower in both sexes of the F_0 generation during the premating phase and the gestation and lactation phases (postmating phase in males) for both matings at 400 ppm (M & F: 5-7%) and 800 ppm (M: 9-19%; F: 5-18%). Similar significant reductions were also observed in the F_{1b} generation, although the reductions were greater (M & F: 5-10% at 400 ppm and M: 26-29%, F: 15-22% at 800 ppm). Food consumption was also significantly reduced in both sexes during these periods at 400 ppm (M: 5-8%; F: 7-19%) and 800 ppm (M: 8-25%; F: 11-31%) in both generations, with the reductions being greater in the F_{1b} generation. Propargite had no effect on male fertility, mating, female fertility and gestation indices. Pup weights were significantly reduced at 400 ppm starting on lactation day 7 and at 800 ppm starting on lactation day 0. By lactation day 21, the pup weights were 8-14% lower (M & F) at 400 ppm and 36-43% lower (M & F) at 800 ppm. There were no treatment-related differences in macroscopic or microscopic lesions. The reproductive NOEL was 80 ppm (4 mg/kg/day) based on the postnatal growth reductions in pups. The parental NOEL was also 80 ppm (4 mg/kg/day) based on reduced parental body weights. This study was considered acceptable to DPR toxicologists based on the FIFRA guidelines.

Diet-Rat

In an ancillary cross-fostering reproduction study, 100, 60 and 120 Crl:CD VAF/Plus® rats/sex were exposed to propargite (89.87% purity) at 0, 400 or 800 ppm (0, 20 or 40 mg/kg/day)[3], respectively, for 70 days prior to delivery (York, 1992). On lactation day 0, litters were cross-fostered to dams in different groups or to other dams within the group. The dams were reassigned to smaller groups of 20, where possible, on the basis of what groups their offspring were born to. There were 7 groups during the lactation period: 1) untreated dams with their own untreated litters, 2) untreated dams cross-fostered to untreated litters, 3) untreated dams cross-fostered to 400 ppm litters, 4) untreated dams cross-fostered to 800 ppm litters, 5) 400 ppm dams cross-fostered to untreated litters, 6) 800 ppm dams cross-fostered to untreated litters and 7) 800 ppm dams with their own 800 ppm litters. Treatment of dams continued for 3 weeks following cross-fostering. Pup weights were significantly reduced in untreated litters cross-fostered to dams treated at 400 ppm (M: 11-14%; F: 10-12%) on lactation days 14-21 and at 800 ppm (M: 17-30%; F: 17-29%) on lactation days 7-21. Reduced pup weights were not observed in treated litters cross-fostered to control dams. Pups weights were significantly reduced (M & F: 2%) on day 0 in litters of dams receiving 800 ppm who also had significantly reduced maternal weights (8%). This suggests that the reduced weights in pups at 800 ppm that were not cross-fostered during lactation was due to a combination of maternal toxicity and the direct consumption of the diet by the pups during the latter half of the lactation period. On the other hand, pup weights were not reduced on day 0 in litters of dams treated at 400 ppm; therefore, reductions in pup weights at this dose level were primarily due to direct consumption of the treated diet by the pups. Since the reduction in pup weights did not occur in the untreated

[3] Estimated assuming for a rat that 1 ppm in the diet is equivalent to 0.05 mg/kg/day (FDA, 1959).

litters cross-fostered to treated dams in the early lactation period when the pups were too young to ingest the diet, the investigators suggested that the reduced pup weights was due to the direct consumption of the treated diet by pups rather than indirect exposure through nursing. However, DPR toxicologists concluded that dam-mediated effects could not be ruled out. Therefore, the NOEL for reproductive toxicity from the previous study was not changed; however, the extent of the concern for reproductive toxicity was reduced since there was no indication of reproductive toxicity during prenatal development.

G. DEVELOPMENTAL TOXICITY

Summary

Two rat and two rabbit teratology studies were available for propargite. All four studies were found acceptable by FIFRA guidelines. Maternal effects included mortalities, clinical signs (bloody nasal discharge, urinary incontinence, diarrhea, soft stools, abnormal respiration, vaginal discharge, adipsia, anorexia, alopecia, depression) and reduced body weights. The lowest maternal NOEL was 2 mg/kg/day based on reduced survival, body weight losses, anorexia and adipsia in rabbits. Developmental effects included abortions, resorptions, reduced fetal viability, minor skeletal variations related to delayed ossification, malaligned or fused sternebrae, hydrocephaly and reduced pup weight. The lowest developmental NOEL was also 2 mg/kg/day based on delayed ossification in rabbits.

Gavage-Rat

Propargite (84-88% purity) was administered by oral gavage to at least 20 pregnant female BLU:(SD) rats/dose at 0 (corn oil), 6, 25 or 105 mg/kg/day on gestation days (GDs) 6-15 (Knickerbocker, 1979). There was evidence of maternal toxicity at 105 mg/kg/day including 2 deaths and numerous clinical signs (bloody nasal discharge - onset GD 6, diarrhea - onset GD 7, soft stools - onset GD 8, urinary incontinence - onset GD 8, vaginal discharge - onset GD day 8, abnormal respiration - onset GD 8 and alopecia - onset GD 9). The deaths occurred on GDs 15 and 16. In addition, one dam at 105 mg/kg/day was sacrificed due to aggressive behavior. Terminal body weights were slightly reduced (3%) at 105 mg/kg/day, but the difference was not statistically significant. No treatment-related increase in external, skeletal or viseral malformations was seen. There was a slight increase in minor skeletal variations at 25 mg/kg/day (missing sternebra, incomplete ossification of vertebrae and extremities, incomplete closure of skull and reduced or missing hyoid bones). DPR toxicologists considered the minor skeletal variations to be a result of delayed ossification which were possible developmental effects because they occurred in the absence of apparent maternal toxicity. The maternal NOEL was 25 mg/kg/day based on the deaths and clinical signs. The developmental NOEL was 6 mg/kg/day based on the skeletal variations. The study was considered acceptable to DPR toxicologists based on the FIFRA guidelines.

Gavage-Rat

In a subsequent study, 45 mated female Sprague-Dawley CRL:CD VAF/Plus rats were administered propargite (85% purity) by oral gavage at 0 (corn oil), 6, 12, 18, 25 and 105

mg/kg/day on GDs 6-15 (Schardein, 1990). Twenty litters per group were collected by C-section on day 20 and the remainder were delivered and raised to weaning. Anogenital and body staining and significantly reduced body weights (5-7%) were observed in the dams at 105 mg/kg/day on GDs 9-20. A reduction in the percentage of live pups delivered and an increase in the number of litters with dead pups during lactation occurred at 105 mg/kg/day. The maternal NOEL was 25 mg/kg/day based on reduced body weights and anogenital staining. The developmental NOEL was also 25 mg/kg/day based on the decreased number of live pups at delivery and reduced survival of pups during lactation. DPR toxicologists found this study acceptable based on FIFRA guidelines.

Gavage-Rabbit

Groups of 17 pregnant female New Zealand White rabbits/dose were administered propargite (85% purity) by oral gavage at 0 (corn oil), 2, 6, 10 or 18 mg/kg/day from GDs 6 through day 18 (Serota *et al.*, 1983). Reduced survival was observed at 6, 10 and 18 mg/kg/day, but was only statistically significant at 18 mg/kg/day (Table 7). There were also two deaths at 0 and 2 mg/kg/day which appear to be related to misdosing based on pathological findings in the trachea (dark red lining or material, thick foamy material) and/or thoracic cavity (red fluid). One rabbit that died at 18 mg/kg/day may have also been misdosed based on dark red material in the trachea. Clinical signs were observed within the first 3 days of dosing at these same dose levels, including adipsia (absence of thirst or abnormal avoidance of drinking of water - onset GD 8) and anorexia (onset GD 7). Since food or water consumption were not measured in this study, these observations were presumably based on full feeders and water bottles. A dose-response relationship was apparent by GD 9 for anorexia and by GD 14 for adipsia. Depression (onset GD 11) and soft feces (onset GD 10) was also observed at 10 and 18 mg/kg/day. Dose-related maternal body weight losses were seen between days 6 and 18 at 6, 10 and 18 mg/kg/day (3%, 8% and 18%, respectively), but they were only statistically significant at 18 mg/kg/day. These body weight losses were seen as early as GD 11[4], but were not as severe (3%, 4% and 9% at 6, 10 and 18 mg/kg/day, respectively). The percentage of resorptions was twice as high at 10 and 18 mg/kg/day compared to controls. The percent fetal viability (number of live fetuses divided by the number of implantations multiplied by 100) was reduced at 10 and 18 mg/kg/day (73.5% and 78%, respectively) relative to controls (88.5%). The differences were not statistically significant, but the investigators considered them treatment-related. The mean pup body weights were also reduced (M: 9%; F: 14%) relative to controls at 18 mg/kg/day. A significant increase in delayed ossification of the skull (Grade 3) occurred at 6 and 10 mg/kg/day. Three fetuses had enlarged, domed heads or hydrocephaly, one at 10 mg/kg/day and the other two at 18 mg/kg/day. The two fetuses at 18 mg/kg/day occurred in the same litter, so the increase at 18 mg/kg/day was only statistically significant when expressed on a pup basis. One of the fetuses at 18 mg/kg/day also had dilated lateral and third ventricles. The other two fetuses (1 at 10 mg/kg/day and 1 at 18 mg/kg/day) had severe delayed ossification of the skull (Grade 2) which was considered an anomaly, rather than a variant. This would suggest that the hydrocephaly may be secondary to the delayed skull ossification, at least in some instances. A significant increase in malaligned or fused sternebrae was found at 10 mg/kg/day. The low incidence rate and lack of statistical significance, of the delayed ossification of the skull and malaligned or fused sternebrae at 18

[4]GD11 was the next time maternal body weights were taken after the first day of dosing, GD6.

Table 7. Possible Adverse Effects in a Pregnant Rabbits Administered Propagite By Gavage During Gestation Days 6-18.[a]

Possible Adverse Effect	Dose Level (mg/kg/day)				
	0	2	6	10	18
Doe Death (%)	2/17 (12%)	2/17 (12%)	3/17 (18%)	4/17 (24%)	13/17* (76%)
Adipsia	6/17 (35%)	3/17 (18%)	7/17 (41%)	11/17 (65%)	15/17* (88%)
Anorexia	6/17 (35%)	5/17 (29%)	8/17 (47%)	11/17 (65%)	15/17* (88%)
Body weight gain days 6-18 (g)	8.0	60.7	-109.6	-312.6	-682.7*
Pups Resorptions (mean #/litter)	1.0	1.0	0.7	1.8	1.5
Live pups (mean #/litter)	7.7	6.6	6.7	5.6	5.3
Body weights (g) M	41.3	44.3	39.7	41.9	37.7
F	39.6	42.3	40.2	42.3	34.2
Hydrocephaly (pups affected) (litters affected)	0/115 0/15	0/92 0/14	0/74 0/12	1/62 1/11	2/21* 1/4
Delayed ossification of skull (pups affected) (litters affected)	5/115 3/15	4/92 3/14	9/74* 6/12	8/62* 4/11	2/21 1/4
Malaligned or fused sternabrae (pups affected) (litters affected)	0/115 0/15	2/92 2/14	2/74 2/12	5/62* 3/11	0/21 0/4

a Serota *et al.*, 1983.
b Incidence on dosing day 4 (GD 9) was 3/16, 0/16, 3/17, 1/17 and 3/16 at 0, 2, 6, 10 and 18 mg/kg/day, respectively.
c Incidence on dosing day 4 (GD 9) was 2/16, 2/16, 4/17, 6/17 and 11/16 at 0, 2, 6, 10 and 18 mg/kg/day, respectively.

mg/kg/day was considered to be due to the small number of fetuses available for examination at this dose level. The investigators considered all these developmental effects, except possibly the hydrocephaly, to be related to maternal toxicity. The delayed ossification in the skull and fused or malaligned sternebrae were usually associated with reduced maternal weight gain or weight loss during treatment. The maternal NOEL was 2 mg/kg/day based on body weight losses and

clinical signs. The developmental NOEL was also 2 mg/kg/day based on delayed ossification of the skull. DPR toxicologists found this study to be acceptable based on FIFRA guidelines.

Gavage-Rabbit

In a second rabbit teratology study, 25 inseminated female New Zealand White (SPF) rabbits/dose were administered propargite (85% purity) by gavage at 0 (corn oil), 2, 4, 6, 8 or 10 mg/kg/day on GDs 7 through 19 (Schardein, 1989). One female each died at 6 and 8 mg/kg/day, but no cause of death was determined. Various clinical signs were observed in the treatment groups, but only the incidence of decreased defecation appeared to be dose related (Table 8). The incidence was significantly different from controls at 6, 8 and 10 mg/kg/day. The earliest onset (GD 9) was at the lowest dose. Due to the later onset in the other groups (Gds 13-14), the decreased defecation was considered a cumulative effect. One rabbit at 10 mg/kg/day was noted as emaciated which may also have been treatment related based on the reduced body weight gains during treatment. The mean body weight gains during the treatment period were reduced at 8 and 10 mg/kg/day, although the differences were not statistically significant. Abortions occurred at 4, 8 and 10 mg/kg/day. The investigators considered only the abortions at 10 mg/kg/day to be treatment related because they occurred at the highest dose level and they were accompanied by other signs of toxicity. DPR toxicologists initially considered the abortions at 4 and 8 mg/kg to be treatment-related, but after submission of additional information (clarification that one doe at 6 mg/kg/day did not abort and one abortion at 8 mg/kg/day was associated with maternal death, missing individual litter data, historical data), the abortions at 4 and 8 mg/kg/day were no longer considered treatment-related by DPR. Since there were no abortions at 6 mg/kg/day, the abortions at 4 mg/kg/day were probably not treatment-related. It is unclear if the one abortion at 8 mg/kg/day that was not associated with maternal death was treatment-related due to the low incidence. This conclusion was also supported by the lack of abortions in an earlier study in which rabbits were dosed up to 18 mg/kg/day without abortions in any group. An increase in fused sternebrae was seen at 10 mg/kg/day. The maternal NOEL was 6 mg/kg/day based on the reduced body weight gains/weight losses at 8 and 10 mg/kg/day and the abortions at 10 mg/kg/day. The developmental NOEL was 8 mg/kg/day based on the increased fused sternebrae. The study was found acceptable by DPR toxicologists based on the FIFRA guidelines.

Table 8. Possible Adverse Effects in a Pregnant Rabbits Administered Propagite By Gavage During Gestation Days 7-19.[a]

Possible Adverse Effect	Dose Level (mg/kg/day)					
	0	2	4	6	8	10
Doe Decreased defecation	5/25^{+++} (20%)	6/25 (24%)	9/25 (36%)	12/25* (48%)	14/25* (56%)	13/25* (52%)
Emaciated	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
Aborted	0/25^{+} (0%)	0/25 (0%)	3/25 (12%)	0/25 (0%)	2/25 (8%)	4/25[b] (16%)
Body weight gain days 7-20 (g)	114	165	119	38	9	-20
Pups - Fused sternebrae (pups affected) (litters affected)	0/106^{+++} 0/17^{++}	2/101 1/15	1/121 1/17	0/139 1/18	2/125 2/18	9/116** 6/16**

a Schardein, 1989.
b Based on Fisher's exact test p= 0.055.
*, ** Significantly different from controls by Fisher's exact test at $p < 0.05$ and 0.01, respectively.
+,++,+++ Significant trend based on the Cochran-Armitage trend test at $p < 0.05$, 0.01 and 0.001, respectively.

III. RISK ASSESSMENT

A. HAZARD IDENTIFICATION

Acute Toxicity

The adverse effects observed in laboratory animals with acute exposure to propargite are summarized in Table 9. In general, the effects that are considered adverse include clinical signs, reductions in body weight and food consumption greater than 10%, and increases in gross and histopathological lesions. Minimal changes in clinical chemistry and hematology values and organ weights without accompanying functional or structural changes are generally not considered adverse. Possible acute effects from propargite included effects seen in the LD_{50}/LC_{50} studies and some findings in the developmental toxicity studies. The effects observed in the LD_{50}/LC_{50} studies included death, clinical signs, reduced body weights, dermal irritation with dermal exposure, gastrointestinal abnormalities, dark red adrenal glands and jaundice with oral exposure and discoloration or red lungs with all routes of exposure. The clinical signs included vocalization, abnormal defecation, decreased urination, inappetence, dehydration, hypothermia, ataxia, hypersensitivity to touch, moist rales, hair loss, scabbing and swelling around mouth, ears, and urogenital areas and staining around nose and urogenital area. Dermal irritation included severe erythema and edema, eschar, fissuring, desquamation, exfoliation and white-yellow exudate. The dose levels were too high in the LD_{50}/LC_{50} studies to establish NOELs for these effects.

The effects observed in the developmental toxicity studies which were considered acute included maternal signs observed within the first 4 days of exposure and fetal effects that could be the result of one or two days of exposure, such as pre- and post-implantation losses, and skeletal and visceral malformations. Various clinical signs were seen in dams/does in several developmental toxicity studies during the first 4 days of treatment. These signs included bloody nasal discharge, diarrhea, soft stools, urinary incontinence, vaginal discharge, abnormal respiration and alopecia in rats and anorexia, and adipsia in rabbits (Knickerbocker, 1979; Serota *et al.*, 1983). Reduced maternal body weight gains were observed in one rat developmental toxicity study and in both rabbit developmental toxicity studies; however, it was unclear if these were acute effects since the maternal body weights were often not measured frequently enough to determine the onset. However, in the one rat study, reduced maternal body weights (5-7%) were observed by treatment day 4 at 105 mg/kg/day (Schardein, 1990). Several fetal effects were noted in the developmental toxicity studies including delayed or incomplete ossification of the vertebrae, extremities, skull and hyoid bones, fused or malaligned sternebrae, hydrocephaly, abortions and reduced fetal viability. It is possible that the skeletal variations, such as delayed ossification, were the result of repeated dosing and/or related to maternal toxicity, but the assumption was made that these variations, especially the delayed ossification, were due to one or two doses since the maternal anorexia occurred very early on in the treatment period. Due to the late occurrence of the abortions (earliest occurrence on treatment day 13 at 10 mg/kg/day) and dead fetuses at term these effects were not considered acute. It appears from the developmental toxicity studies that rabbits are more sensitive to propargite than rats. The lowest NOEL in the developmental toxicity studies was 2 mg/kg based on anorexia in pregnant rabbits

Table 9. Acute and Short-term Effects of Propargite and Their Respective NOELs and LOELs

Species	Exposure	Effect	NOEL (mg/kg)	LOEL (mg/kg)	Ref.[a]
Inhalation					
Rat[b]	Single, 4-hour nose only	Death, clinical signs, ↓ body wts., discolored lungs	-----	0.31 (mg/L)	1*
Oral					
Rat[b]	Single, gavage	Numerous clinical signs[c]	-----	2000	2*
Rat[d]	10 days, gavage	Maternal: Clinical signs[e] Fetal: Skeletal variation related to delayed ossification	25	105	3*
Rat[d]	10 days, gavage	Maternal: ↓Body weight (day 4)	25	105	4*
Rabbit[d]	**13 days, gavage**	**Maternal: Anorexia (day 2)** **Fetal: Delayed ossification**	**2**	**6**	**5***
Rabbit[d]	13 days, gavage	Fetal: Fused sternebrae	8	10	6*
Dermal					
Rat[b]	Single, 24-hr	Clinical signs, dermal irritation, reddened lungs	-----	4000	7

a References: 1.Hoffman, 1992a; 2.Kiplinger, 1993a; 3. Knickerbocker, 1979; 4. Schardein, 1990; 5. Serota *et al*., 1983; 6. Schardein, 1989.

b LC_{50}/LD_{50} study

c Clinical signs include vocalization, abnormal defecation, decreased urination, inappetance, dehydration, hypothermia, ataxia, hypersensitivity to touch, moist rales, hair loss, scabbing and swelling around mouth, ears, and urogenital areas, staining around nose and urogenital area.

d Developmental toxicity study: All fetal effects were considered acute effects; however, only maternal effects observed within the first few days of exposure were considered acute exposure.

e Bloody nasal discharge (day 1), diarrhea (day 2), soft stools (day 3), urinary incontinence (day 3), vaginal discharge (day 3), abnormal respiration (day 3) and alopecia (day 4).

* Acceptable study based on FIFRA guidelines

that was observed as early as treatment day 2 at 6 mg/kg/day (Serota *et al.*, 1983). A dose-related trend in the incidence of anorexia was observed by day 4 of dosing. Although adipsia was observed as early as day 3 of treatment, a dose-related trend in the incidence was not apparent until day 9 of dosing. The treatment-related trend in anorexia was supported by maternal body weight losses in this study between treatment days 1 and 6. Delayed ossification was also observed at this dose level in the fetuses. The delayed ossification may be related to the maternal weight losses. The NOEL of 2 is supported by a benchmark dose (BMD) analysis of the incidence of anorexia on day 4. Using U.S. EPA's BMDS software, the model with the best fit was the quantal quadratic model with the lower limit of the BMD at the 5% response level ($BMDL_{05}$) equal to 3.2 mg/kg/day. Other quantal models estimated the $BMDL_{05}$ between 0.9 and 2.1 mg/kg/day. Interestingly, a BMD analysis of the maternal body weight changes between treatment days 1 and 6, resulted in a $BMDL_{05}$ of 1.7 mg/kg/day based on the Hill model, the only continuous model that resulted in meaningful results. Although a higher NOEL was observed in a similar rabbit developmental toxicity study that was conducted later by Schardein (1989), there

were no major deficiencies in the Serota *et al.* study that would justify dismissing the findings in this study. Therefore, this study was selected as the definitive study for evaluating acute dietary and drinking water exposure to propargite with a critical NOEL of 2 mg/kg based on the anorexia in pregnant rabbits and delayed ossification of the skull in fetuses.

Subchronic Toxicity

The effects observed in laboratory animals after subchronic exposure to propargite are summarized in Table 10. The most common systemic effect with exposure to propargite, regardless of route, was reduced body weights or body weight gains. Reductions in food consumption were also seen. Changes in hematological and clinical chemistry values were observed in a dermal study in rabbits, including increased ASAT, globulin, white blood cell count, segmented neutrophils, monocytes and platelets, and reduced albumin and calcium. The veterinary pathologist for one study suggested that the hematological and clinical chemistry changes may be related to the dermal irritation (Bailey, 1987). Increased relative liver, kidney, adrenal gland and/or gonad weights were observed in several studies. It is unclear if these organ weight changes are related to reduced body weights or organ toxicity. Pathological findings in these subchronic studies included increased pigment in reticuloendothelial cells of the liver and hemosiderosis of the spleen in dogs and chronic nephritis, liver inflammation and necrosis in rabbits.

In addition to the standard subchronic toxicity studies, Table 10 includes several developmental toxicity studies where maternal effects were observed after short-term exposure for 1 to 2 weeks. The systemic maternal toxicity observed after short-term exposure to propargite included death, bloody nasal discharge, diarrhea, soft stools, urinary incontinence, anogenital staining, vaginal discharge, abnormal respiration, anorexia, adipsia and alopecia (Knickerbocker, 1979; Serota *et al.*, 1983; Schardein, 1990). Reduced maternal weight gain or weight loss were also seen (Schardein, 1989 & 1990; Serota *et al.*, 1983). Increased abortions and dead fetuses were also seen and were considered the result of cumulative toxicity (Schardein, 1989 & 1990; Serota *et al*., 1983). The lowest NOEL in an acceptable developmental toxicity study was 2 mg/kg/day based on reduced survival, anorexia, adipsia and reduced body weight in pregnant rabbits (Serota *et al.*, 1983).

Any subchronic effects observed in reproductive toxicity studies were also included in Table 10. The effects observed in the parental generations of the reproductive toxicity study for propargite included reduced body weights and food consumption. The effects observed in pups were reduced postnatal growth. In the one acceptable study, the NOEL of 4 mg/kg/day (80 ppm) was based on reduced body weights (5-10%) (Kehoe, 1990). The reproductive NOEL in this study was also 4 mg/kg/day based on reduced postnatal growth.

Reductions in body weight appears to be the most sensitive endpoint with subchronic exposure to propargite. Rabbits appear to be more sensitive than rats and dogs to the short-term exposure to propargite based on a comparison of the LOELs. The lowest systemic NOEL in an acceptable subchronic toxicity study was 1 mg/kg/day based on reduced body weights (F: 14-

Table 10. Short-term or Subchronic Effects of Propargite and Their Respective NOELs and LOELs

Species	Exposure	Effect	NOEL (mg/kg/day)	LOEL (mg/kg/day)	Ref.[a]
Oral					
Rat[b]	10 days, gavage	Maternal: Deaths, clinical signs	25	105	1*
Rat[b]	10 days, gavage	Maternal: Anogenital staining, ↓body weights Fetal: ↓Survival	25	105	2*
Rabbit[b]	14 days, gavage	Maternal: ↓ Survival, anorexia, adipsia, ↓ body wt. gain	2	6	3*
Rabbit[b]	14 days, gavage	Maternal: ↓Defecation, ↓ body weight gain	6	8	4*
Rat[c]	2-gen., 10 wks premating, diet	Parental: ↓Body weights Pups: ↓ Postnatal growth	4	20	5*
Rat	90-days, diet	↓ Body wt., ↓food consumption	40	110	6
Dog	13 weeks, diet	↓ Body wts. and food cons., ↑ASAT, ↑ liver wt., ↑ pigment in reticuloendothelial cells of liver	-----	50	7
Dermal					
Rabbit	6 hrs/day, 5 days/wk, 3 wks	Systemic: ↓Body wts., changes in clinical chemistry and hematology values, ↑ relative liver and kidney wts. Local: Dermal irritation	1 (0.01)[d]	10 0.1	8*
Rabbit	6 hrs/day, 5 days/wk, 3 wks	Systemic: Chronic nephritis, inflammation of liver Local: Dermal irritation	-----[e] (0.01)[d]	100 0.1	9

a References: 1. Knickerbocker, 1979; 2. Schardein, 1990; 3. Serota *et al.*, 1983; 4. Schardein, 1989; 5. Kehoe, 1990; 6. Carson, 1964; 7. Hazelton, 1968; 8. Bailey, 1987; 9. Goldenthal, 1989.
b Developmental toxicity study: Only maternal effects observed after the first few days were included.
c Reproductive toxicity study
d NOEL estimated by dividing the LOEL by an uncertainty factor of 10.
e The liver and kidney were not examined microscopically at 0.1, 1 or 10 mg/kg/day.
* Acceptable study based on FIFRA guidelines

20%), changes in clinical chemistry and hematology values, and increased relative liver and kidney weights in rabbits after a 21-day dermal exposure. Dietary and drinking water exposure to propargite did not vary significantly with season; therefore, a subchronic NOEL was not selected for this purpose. However, this 21-day dermal study could be used for evaluating seasonal occupational exposure which will be addressed in an addendum to this RCD.

Chronic Toxicity

The effects observed in laboratory animals from chronic exposure to propargite are summarized in Table 11. Reduced body weights (M: 4-58%, F: 2-50%) and food consumption (M: 2-60%, F: 2-67%) were the most prevalent effect observed with chronic exposure. Reduced survival was observed in two rat studies. Changes in hematological values were seen in both rats and dogs. These included significant increases in platelets and reticulocytes and significant decreases in RBC counts, hematocrit and hemoglobin values. Changes in clinical chemistry values were also seen in rats. This included significant reductions in glucose, total protein, globulin, calcium, ASAT, ALAT and a significant increase in albumin levels. Most of these changes were of uncertain toxicological significance, although the reductions in many of the clinical chemistry values may be related to reduced food consumption. Increases in organ weights were observed in mice, rats and dogs, including absolute adrenal gland (F: 46-50%), thyroid (F: 60%) and uterus (F: 75%) weights and relative liver (M: 38-53%, F:17-38%), kidney (M: 10-12%, F: 31-35%), brain (M: 12%, F: 33%), adrenal gland (M: 46-55%, F: 46-53%), testes (M: 68%) and thyroid/parathyroid (M: 53%, F: 44-64%) weights. Decreases in the absolute weight of a few organs were seen, including the heart (M: 39%, F: 40%), kidney (M: 34%, F: 33%) and ovaries (F: 52%) weights. Most of these organ weight changes were probably related to body weight reductions. Microscopic lesions in the lungs (congestion or inflammation), thymus (involution) and bone marrow (atrophy) were seen in one dog study at 1250 ppm and higher.

Table 11. Chronic Effects of Propargite and Their Respective NOELs and LOELs

Species	Exposure	Effect	NOEL (mg/kg/day)	LOEL (mg/kg/day)	Ref.[a]
Mouse	18 months, diet	None	150	-----	1*
Rat	2 years, diet	↓ Survival, ↓body wts., ↓food consumption (Miscellaneous sarcomas)	45 (15)	100 (45)	2
Rat	**103-104 weeks, diet**	**↓Body wts., ↓food consumption, (Sarcomas of jejunum)**	**3.8 (3.8)**	**19.2 (19.2)**	**3***
Rat	2 years, diet	↓ Survival, ↓body wts., ↓food consumption, ↑ relative organ wts. (Sarcomas of sm. intestine and abdomen)	----- (-----)	36.3 (36.3)	4
Dog	2 years, diet	None	22.5	-----	5
Dog	1 year, diet	↓ Body wts., ↓ RBC, Hct and Hgb, ↑ platelets, ↑ relative liver wts., involution of the thymus	4	31	6*

a References: 1. Cox and Re, 1979; 2. FDRL, 1966; 3. Trutter, 1991; 4. Goldenthal, 1993; 5. FDRL, 1966; 6. Atkinson, 1991.

* Acceptable study based on FIFRA guidelines

Mice appear to be relatively less sensitive to chronic exposure to propargite than rats and dogs based on the available studies. The chronic toxicity study in rats conducted by Trutter (1991) was selected as the definitive study for evaluating chronic dietary and drinking water exposure to propargite since it had the lowest chronic NOEL and it met FIFRA guidelines. The critical NOEL for chronic exposure was 3.8 mg/kg/day based on reduced body weights and food consumption. A similar NOEL of 4 was observed in a 1-year dog study based on reduced in body weights, hematological changes, increased relative liver weight and involution of the thymus.

Oncogenicity - Weight of Evidence

There is evidence that propargite is oncogenic based on an increase in undifferentiated sarcomas of the jejunum in Sprague-Dawley rats (Table 6) (Trutter, 1991). The increases in this rare tumor were statistically significant by pairwise comparison with controls in males at 400 ppm and in both sexes at 800 ppm. There was also a significant positive trend for these tumors in both sexes. Ulceration and ectatic mucosal glands at the tumor site were often associated with these tumors. In another study with Wistar rats (FDRL, 1966), there was an apparent dose-related increased in sarcomas of the intestine with characteristics resembling the undifferentiated sarcomas observed in the jejunum of Sprague Dawley rats in the Trutter (1991) study. These sarcomas included spindle cell sarcomas, myosarcomas and osseous sarcomas. These sarcomas occurred in 1 male at 300 ppm, 3 males and 1 female at 900 ppm and 3 males and 1 female at 2000 ppm.

There was a shortening of the time to tumor when males at 400 and 800 ppm from the Trutter (1991) study were compared. The average time to tumor at 400 and 800 ppm was 99.5 and 90.2 weeks, respectively. The shortest time to tumor (65 weeks) was in a male at 800 ppm. The jejunal sarcomas were considered the cause of death in 8 of 11 rats at 400 ppm and 20 of 24 rats at 800 ppm.

A consultant pathologist noted that propargite was ulcerogenic at the doses that caused tumors in the Trutter (1991) study, allowing the lumenal exposure of the submucosal mesenchymal cells. He examined 10 additional jejunal step section in 26 males at 0 and 800 ppm from this study. At 800 ppm, 5 males had focal epithelial necrosis and 2 of these were large ulcers with submucosal stromal and inflammatory responses. The smallest lesions were crypt abscesses filled with necrotic cell debris and surrounded by attenuated epithelium, portions of which were necrotic. No crypt abscesses, ulcers, epithelial necrosis or other similar lesions were found in the control animals.

To evaluate the possible role necrosis and ulceration had in the oncogenic process, a cell proliferation study was conducted (Eldridge, 1994). Male and female Sprague-Dawley rats and male CD-1 mice were fed propargite in the diet for up to 4 weeks. There was no significant increase in cell proliferation in the jejunum in male rats at 80 ppm, female rats at 40 ppm, or male mice at 1000 ppm at either week 1 or 4. However, there was a significant increase in cell proliferation in the jejunum in both sexes of rats at 800 ppm at week 1. The cell proliferation was also significantly increased in males at 800 ppm at week 4, but was not considered

biologically significant by the investigator since the increase was less than 2-fold over the controls. The investigator noted that, although the increase in cell proliferation was transient, transient increases in cell proliferation have been observed with mitogenic nongenotoxic carcinogens. A second cell proliferation study was conducted to evaluate the apparent lack of response in the Wistar rat (Eldridge, 1995). No biologically significant increase in cell proliferation was observed in either sex at 900 ppm, although a statistically significant increase in the outer longitudinal layer of the tunica muscularis was seen in females at 900 ppm.

The consulting pathologist also suggested that the propylene oxide stabilizer in technical grade propargite formulations may have been responsible for the tumors since it is genotoxic. To investigate this further, another 2-year chronic toxicity study was conducted in which 60 male Sprague-Dawley rats were fed reformulated technical grade propargite in the diet at 0 and 800 ppm. An increase in undifferentiated sarcomas in the duodenum, jejunum and soft tissue of the abdomen were observed. Most of the treated rats that died or were killed in a moribund condition had undifferentiated sarcomas (19/28) compared to controls (4/17).

The genotoxicity studies for propargite were all negative except one marginally acceptable HPRT gene mutation assay in CHO cells. In this study, the propargite in the dosing solution had either broken down or reacted with the vehicle, DMSO. More recent, well-conducted HPRT gene mutation assays were negative using either acetone or DMSO as the vehicle at similar concentrations. The other negative genotoxicity studies included reverse mutation assays with *Salmonella typhimurium* (strains TA1535, TA1537, TA1538, TA98 and TA100), *Saccharomyces cerevisiae* (D4 strain) and *Escherichia coli* (WP2 *hcr* strain), an *in vitro* cytogenetics assay with CHO cells, an *in vivo* micronucleus cytogenetics assay in mice, a rec assay with *Bacillus subtilis* H17 (rec^+) and M45 (rec^-) strains and an unscheduled DNA synthesis (UDS) assay with rat primary hepatocytes. The two chromosomal aberration studies and the UDS assay were found acceptable by DPR toxicologists.

Quantitative Assessment of Oncogenic Effects

Based on the weight of evidence, DPR considered propargite to be oncogenic because 1) the increase in tumors was statistically significant by pairwise comparison with controls in both sexes; 2) the incidence of tumors exhibited a significant dose-related trend in both sexes; 3) jejunal sarcomas are a rare tumor type; 4) sarcomas of the intestine and other tissues were observed in two other supplemental studies (FDRL, 1966; Goldenthal, 1993); and 5) there was a shortening of the time to tumor. There was some evidence to suggest that propargite may be acting by a threshold mechanism: 1) transient increase in cell proliferation and 2) essentially all negative genotoxicity studies. However, by itself this evidence was not considered sufficient to justify using a threshold approach. Therefore, a non-threshold mechanism was assumed as a default. The oncogenic potency of propargite was calculated using the incidence of jejunal sarcomas in male Sprague Dawley rats in the study conducted by Trutter (1991).

U.S. EPA classified propargite as a B_2 carcinogen based on the jejunal tumors in rats (U.S. EPA, 2001a). There was a dose-related increase in deaths at the high dose which suggests that the Weibull time-to-tumor model would be the most appropriate model. Although the

registrant argued with U.S. EPA that the Weibull time-to-tumor model was not the most appropriate model when the deaths were due to tumors, their argument was not persuasive since no clear explanation was given as to why it was inappropriate (U.S. EPA, 2001b). The registrants had the K.S. Crump Group of ICF, the developers of the Weibull time-to-tumor model, evaluate the tumor data. These consultants compared the fit of the Weibull time-to-tumor model with a multistage quantal model from Tox_Risk software using the Akaike Information Criterion (AIC) values. The fit of the multistage quantal model was very good whereas the fit for the Weibull time-to-tumor model was poor. Because the fit was so poor for the Weibull time-to-tumor model, the confidence interval and corresponding upper confidence limit on risk were quite large. The consultants determined they were unable to get a good fit with the Weibull time-to-tumor model because the software was unable to optimize the model parameters. They were able to "reparameterize" the model and get a better fit; however, they found the AIC still indicated the multistage quantal model had a better fit. Based on this information, U.S. EPA decided to calculate the oncogenic potency of propargite using the multistage quantal model. They calculated the Q_1* (i.e., 95th upper bound estimate for potency) for propargite to be 3.3 x 10^{-2} $(mg/kg/day)^{-1}$.

Since the developer of the software indicated that there is a poor fit with Weibull time-to-tumor model due to its inability to optimize the model parameters and it is not possible for DPR to "reparameterize" the model, DPR elected to use a multistage linear model, Global86, to estimate the oncogenic potency of propargite. The incidence of tumors was expressed in terms of rats at risk (i.e., rats that survived 52 weeks on the study). The dosages for male rats (0, 2.4, 3.8, 19.2 or 38.9 mg/kg/day) were first converted to human equivalent dosages (0, 0.7, 1.2, 5.8 or 11.8 mg/kg/day) by multiplying by an interspecies scaling factor of body weight to the 3/4 power $[(BWt_A/BWt_H)^{0.25} = (0.6 \text{ kg}/70 \text{ kg})^{0.25} = 0.304]$. The estimated oncogenic potency for propargite ranged from 5.9 x 10^{-3} $(mg/kg/day)^{-1}$ for the maximum likelihood estimate (MLE) to 2.6 x 10^{-2} $(mg/kg/day)^{-1}$ for the 95th percent upper bound (95% UB).

B. EXPOSURE ASSESSMENT

Dietary Exposure Assessment

Introduction

The Department of Pesticide Regulation conducts acute and chronic dietary exposure assessments to evaluate the risk of human exposure to a pesticide in food (Bronzan and Jones, 1989). Two separate approaches are used to estimate the risk: (1) risk is determined for the total dietary exposure based on measured residue levels on all label-approved commodities and (2) risk is estimated for exposure to an individual commodity at the tolerance level (see Tolerance Assessment section).

Dietary exposure is a product of the amount of food that is consumed and the concentration of the pesticide residue in that food. The total exposure in an individual's diet

during a defined period of time (e.g., a day) is the sum of exposure from all foods (in various forms and as ingredients in food items) consumed within that period:

$$Exposure = \sum_{i=1}^{n} \left(residue_i \ x \ consumption_i \ of \ foods \right)$$

where *n* is the number of food items in the diet.

Consequently, two distinct pieces of information are required to assess the dietary exposure: (1) the amount of the pesticide residue on food and (2) the food consumption. For estimating the acute exposure, the highest residue values at or below the tolerance, or the distribution of residues are considered. In contrast, for chronic exposure, the mean residue values are appropriate. Finally, acute exposure is calculated on a per-user basis (i.e., including in the distribution of exposure only the days of survey that at least one commodity with potential pesticide residues is consumed). Chronic exposure to pesticides is generally calculated using per-capita mean consumption estimates to include the entire population.

Dietary Exposure

The acute and chronic dietary exposure analyses were conducted using the Dietary Exposure Evaluation Model (DEEM™, version 7.74) software program developed by Novigen Sciences, Inc. DEEM™ calculates acute and chronic exposure estimates for 18 different population subgroups, including nursing or non-nursing infants less than 1 year old, children ages 1-6 years old or 7-12 years old, pregnant or nursing women, and seniors 55 years and older. The Acute Analysis program also allows for calculation of exposure for custom populations, such as workers, ages 16 years and older. The Acute Analysis program estimates the distribution of exposure per user-day (i.e., the percentile exposure for only individuals that consume at least one commodity on which the pesticide of concern is used on that survey day). The Acute Analysis estimates exposure either using a deterministic approach (i.e., a single residue value or point estimate for each commodity) or a probabilistic approach (i.e., Monte Carlo method where residue and consumption values are randomly selected from different distribution curves for each commodity). In the deterministic approach, the distribution of exposure is calculated by multiplying the single residue value and the consumption distribution. In the probabilistic approach, the distribution of exposure is calculated by multiplying the distribution of residue and the distribution of consumption (Petersen *et al.*, 2001). Since the probabilistic approach is more time consuming, it is only used if the margins of exposure are inadequate using the deterministic approach and/or there is sufficient residue data to describe the distributions. The Chronic Analysis estimates the annual average exposure per capita using point estimates that represent the average residue values. The chronic analysis estimates the average exposure of all surveyed individuals in a population subgroup at the average pesticide residue. The residue values for both acute and chronic exposure can be adjusted by percent crop treated; however, DPR generally only adjusts the acute values if the Monte Carlo method is used. In this dietary exposure assessment, the residue values were adjusted for percent crop treated based on the values used by U.S. EPA in their dietary exposure assessment for propargite (U.S. EPA, 2000).

In the Acute Analysis, the Critical Exposure Commodity (CEC) analysis provides consumption records for individuals at the high end of dietary exposure (in the top 5% or less).

The CEC analysis also identifies the commodities contributing to the high end of the dietary exposure. The records include the amount of food(s) consumed, body weight, age, residue values and the exposure estimate by food. The CEC analysis provides the means to identify high contributing commodities and any apparent error in the consumption database (e.g., unreasonable body weight at a given age). A detailed description on the CEC analysis is provided in the DEEM™ manual (Kidwell *et al.*, 2001). In the Chronic Analysis, the Critical Commodity Contribution (CCC) analysis performs a similar analysis; however, with chronic exposure the contributing commodities identified are based on the average consumption of the population not the consumption at the high end.

Consumption Data

The United States Department of Agriculture (USDA) directs the Continuing Survey of Food Intakes by Individuals (CSFII), which analyzes the food intake and adequacy of the diets of various population subgroups. The purpose of the CSFII is to analyze food intake every few years to provide up-to-date information on the adequacy of the diets of various population groups and early indications of dietary changes. Individual intake data are collected using both a 1-day recall and a 2-day record protocol. The surveys were conducted in all months of the year. In each year, approximately 5,500 participants in 62 geographical areas were surveyed. The consumption data used in this risk assessment were the CSFII 1994-98 data which were collected from January 1994 to February 1997 (referred to as 1994-96) and from December 1997 to December 1998 (referred to as 1998). This is the preferred consumption data since it is the most recent and representative consumption data. These data provide information on 2-day food intake by 20,607 individuals of all ages from 62 geographical areas. The 1994-96 data included 4,253 children, ages 0 to 9 years old. The 1998 CSFII data included an additional 5,559 children of the same age to increase the database for dietary patterns of infants and children in response to the Food Quality Protection Act of 1996.

Residue Data

The federal and state monitoring programs analyze food samples at produce markets and chain store distribution centers close to the consumer level. Recent, multi-year (3-5 years) residue data are preferred. The USDA Pesticide Data Program (PDP) is the most representative monitoring residue data because it is designed to obtain residue data for risk assessments. The PDP samples are collected in ten states, including California. When a sufficient number of samples (e.g., 30 or more) is analyzed in California and the LOQ is also lower than the other USDA national contract laboratories, the California only data can be used instead of the nationwide data.

DPR has two major sampling programs: priority pesticide and marketplace surveillance. DPR monitoring programs may not be representative because they focus on commodities with known violations (DPR, 1994-2002). In addition the residue limit of quantitation (LOQ) may be high. However, data from the DPR monitoring programs may be useful when PDP data are not available.

The U.S. Food and Drug Administration (FDA) Regulatory Residue Monitoring Program analyzes domestic and imported foods for pesticide residue to enforce the tolerances set by U.S. EPA. Thus, the residue data may not be representative. In addition, residue information may be incomplete for conducting a distribution (e.g., only a range of pesticide concentrations on a particular food is provided; LOQ is not indicated, etc.). FDA data may be useful when PDP and DPR data are not available.

The task force monitoring studies are conducted by manufacturers of a particular pesticide(s). In most cases, these food surveys are designed to determine the residues on specified commodities in response to the U.S. EPA Data Call-In Notices. Samples are usually collected at the produce markets, chain store distribution centers and/or at the farm gates. The task force studies most closely approximates the PDP sampling and may be representative in that they analyze a large number of samples of high consumption commodities and generally have a low LOQ. However, the duration of task force studies is generally short (e.g., 1 year) unlike the multi-year analysis by the PDP.

Other sources for residue data include field trial studies, use of surrogate commodities, and tolerances, in that order of preference. The field trial studies are submitted to DPR by pesticide manufacturers for support in the setting of tolerances (U.S. EPA, 1982). These studies are usually conducted under the highest application rate permitted by the label conditions and, as a result, the residue data may likely consist entirely of upper-end pesticide concentrations. When residue data are not available from monitoring and field trial studies, residues reported for similar foods can be used as surrogates. The choice of the most appropriate surrogate commodity should be based on the classification or grouping of related raw agricultural commodities (RAC) into crop groups, established in 40 CFR 180.40, and according to the agricultural practices specified in the product label. The residue levels are set at the tolerance level when no monitoring or field trial data are available and there is no suitable surrogate commodity. The tolerance is the legal maximum residue concentration of a pesticide on a RAC or processed food. The tolerances are established by the U.S. EPA at levels necessary to allow for the maximum application rate and frequency which most likely do not reflect the actual pesticide use pattern. Therefore, use of the tolerances for residue levels will most likely overestimate the residue levels.

Since dietary exposure assessments can be very labor intensive, DPR toxicologists use a tiered approach with additional refinements when the risk for adverse health effects in humans is considered too high based on the criteria described in the risk appraisal section. Some of the more common refinements to the exposure estimate are: 1) use of residue monitoring data where commodities are analyzed closer to the point of consumption, 2) use of residue monitoring data with a lower detection limit (which is important when no residues are detected), and 3) adjusting for the percent of a crop that is treated with a pesticide. The initial dietary analysis for propargite using the tolerances was considered as Tier 1. The tiered approach for acute dietary exposure begins with the point estimates, which are generally less time-consuming. Since the estimated acute and chronic dietary exposure appear too high based on the criteria described in the Risk Characterization and Risk Appraisal sections, the dietary exposure was further refined.

In the Tier 2 analysis, the residue values from DPR's and PDP's market basket surveys were considered. DPR monitored for propargite in their market basket surveys during only one year, 1996. During this year only 18 samples were tested: 12 grape samples, 5 nectarine samples and 1 sweet corn sample. Due to the small number of DPR samples monitored, most of the residue values for commodities came from PDP's monitoring programs from 1995 to 2001 (USDA, 1997, 1998a&b, 2000, 2001, 2002 & 2003). Other benefits of using the PDP data include: 1) the commodities were analyzed closer to the point of consumption than DPR and 2) the commodities are usually washed and peeled if normally consumed that way. When sufficient data were available (i.e., > 30 samples), PDP data from California were used exclusively since they usually had a lower LOQ. Even the PDP data were limited in that most commodities were analyzed for propargite only 1-3 years. The acute and chronic residue values used from the PDP data are summarized in Table 12. The acute residue value was the highest detected residue value if a point estimate was used or a residue value from a distribution if a Monte Carlo analysis was used. Although there were sufficient numbers of samples to generate files for Monte Carlo analysis, for most of the commodities there were no detectable residues so a point estimate equivalent to the LOQ was used instead. For the chronic dietary assessment, point estimates were used for all the commodities with the chronic value set at the mean or average residue level. If there were no residues detected, then the residue level is set at ½ of the LOQ. Based on the percent crop treated (PCT), some of the samples with non-detectable residues were set to zero. Therefore, some of the chronic or mean residue values were less than ½ of the LOQ. The PCT information for various commodities was obtained from BEAD data presented in U.S. EPA's dietary exposure assessment for propargite (U.S. EPA, 2000). The PCT values used for the commodities where there was PDP data are presented in Table 12. PCT was not applicable to meat, milk, poultry and eggs.

Generally, residue data were not available for processed commodities. There were a few exceptions: grape juice, orange juice and peanut butter. The PCT was not used with these processed commodities since they were considered blended and the residue measured should represent the blended commodity. When no residue data were available for processed commodities, residues were estimated from the fresh commodity by multiplying by the default adjustment factors that account for the loss of water. Since other physical properties of propargite could affect whether it concentrates in processed foods, these residue levels are only theoretical. Nonetheless, if the residues in processed commodities were higher than the tolerance for the RAC, they would be considered illegal since no food additive tolerances were established for these commodities. Therefore, if the resultant residue in the processed commodity was greater than the tolerance, the residue was set to the tolerance and the adjustment factor was set to 1. In the case of peanut butter, the processed commodity was used to estimate the residues in the whole hulled peanuts and peanut oil.

For a few commodities where there was no monitoring data (grapefruit, lemons, limes and tangerines), a surrogate crop (oranges) was used instead. The BEAD PCT estimates for some of these other commodities (lemons = 1%) were slightly different than oranges (2%), so these were used even though the residue value on the whole fruit was the same. Grapefruit had the same PCT as oranges and there were no BEAD PCT estimates for limes or tangerines. Therefore, limes were assumed to have the same PCT as lemons and tangerines the same PCT as oranges. Sweet corn was used as a surrogate for other corn commodities using the same PCT.

Table 12. Propargite Residues in Food Commodities from PDP's Monitoring Programs from 1995 to 2001

Raw Agricultural Commodity	No. of Samples	Acute Value[a] (ppm)	Chronic Value[b] (ppm)	Comment
Beef, adipose[c]	291	0.024	0.012	2001, national, PCT not applicable
Beef, liver[c]	311	0.0096	0.0048	2001, national, PCT not applicable
Beef, muscle[c]	309	0.0086	0.0043	2001, national, PCT not applicable
Corn, sweet[c]	292	0.02	0.0001	1995-6, 2001 CA only, 1% PCT
Grapes	258	0.112	0.005	1996, 2000 CA only, 12% PCT[d]
Grape juice[c]	349	0.02	0.0007	1998-9 CA only, PCT not applicable
Milk[c]	382	0.03	0.015	1996-8 CA only, PCT not applicable
Nectarines	196	1.2	0.128	2000-1 CA only, 79%/39% PCT[e]
Oranges[c]	1,068	0.02	0.0002	1998,2000-1 CA only, 2% PCT
Orange juice[c]	368	0.02	0.0002	1997-8 CA only, PCT not applicable
Peanut butter[c]	716	0.013	0.000065	2000, national, PCT not applicable
Potatoes, sweet[c]	418	0.02	0.0002	1996-8, CA only, 2% PCT
Potatoes, white[c]	316	0.02	0.0002	2000-1, CA only, 2% PCT
Poultry, adipose[c]	631	0.033	0.0165	2000-1, national, PCT not applicable
Poultry, liver[c]	634	0.033	0.0165	2000-1, national, PCT not applicable
Poultry, muscle[c]	299	0.033	0.0165	2000-1, national, PCT not applicable

a The acute value is the highest residue level detected in any sample.

b The chronic value is the mean where the samples with non-detectable residues are set at ½ of the LOQ. Where percent crop treated (PCT) information was available, some of the samples were set to zero based on the PCT.

c There were no-detectable residues, so the acute value was set at the LOQ and the chronic value at ½ the LOQ.

d PCT was used for both acute and chronic analysis since RDF file was used for this commodity. All grape forms were considered partially blended so the same PCT was used for acute and chronic analysis. The grape residue data was used to estimate raisin residues with a different PCT, 41%. Therefore, the resulting chronic value was 0.008 ppm.

e PCT was used for this commodity with acute analysis due to use of RDF file. The acute and chronic PCT were 79% and 39%, respectively, based on the maximum and average PCT estimates from BEAD.

For other commodities where there was no monitoring data and no good surrogate crop, field trial data was used when available. Cottonseed was the only commodity that had adequate field trial data submitted to DPR. The residues for propargite in all the cottonseed samples in the field train study were less than the LOQ, 0.05 ppm. Therefore, the acute and chronic value were set to 0.05 and 0.0005 ppm, respectively. The BEAD estimated average PCT for cotton was 2%.

U.S. EPA reported residues for peppermint and spearmint of 2.73 and 4.73 ppm, respectively, in their dietary exposure assessment based on field trial data they received from the registrant (U.S. EPA, 2000). Since the tolerances were so high for mint, 50 ppm, their residue values were based on the field trial data submitted to U.S. EPA rather than the tolerance. These values were used for both acute and chronic since there was no information provided as to

whether these were average or high values. The BEAD estimated average PCT for mint was 22% which was used for both types of mint.

If there were no monitoring data, appropriate surrogate data or field trial data, the residue levels were assumed to be at the tolerance level for acute exposure and ½ of the tolerance level for chronic exposure (CFR, 2002). The residue values were based on the tolerance levels for the following commodities: almonds (0.1 ppm), dried beans (0.2 ppm), hops (15 ppm), sorghum (10 ppm), dried tea (10 ppm), and walnuts (0.1 ppm). The BEAD estimated average PCTs were 35% for almonds, 2% for dried beans, 5% for hops, 1% for sorghum, 6% for dried tea and 25% for walnuts.

Acute Dietary Exposure

As mentioned, a tiered approach was used in the dietary exposure assessment. The Tier 1 analysis consisted of setting the residue values for all the commodities at their respective tolerance levels. In the Tier 2 analysis, residue values were based on PDP, surrogate or field trial data. Since the acute exposures were still unacceptable (Margin of Exposure < 500 at 99th percentile) with the Tier 2 analysis, a Tier 3 analysis was performed which consisted of substituting the field trial residue values that U.S. EPA used for mint in their dietary exposure assessment for propargite. The acute dietary exposure analysis was still too high with the Tier 3 analysis; therefore, a Tier 4 analysis was conducted with a Monte Carlo analysis of those commodities with detected residues and more than 30 samples analyzed. The BEAD estimated maximum PCT was used in the Monte Carlo analysis to set some of the non-detectable residues to zero instead of the LOQ for commodities in the residue file. The results of the Tier 4 analysis are shown in Table 13. The exposure estimates at the 99.9th percentile of user-day exposure for all specific population subgroups are presented in Table 13. The 99.9th percentile exposure estimates ranged from 1.66 μg/kg/day for pregnant, non-nursing females 13 years and older to 6.81 μg/kg/day for children ages 1-6 years old.

Chronic Dietary Exposure

A Tier 3 analysis is the highest level of refinement possible with chronic dietary exposure assessment. However, unlike the acute analysis, the PCT was used with the point estimates. The BEAD estimated average PCT was used with the chronic analysis. A Tier 3 analysis was necessary with propargite due to the oncogenicity concern. The mean potential chronic dietary exposure ranged from 0.07 μg/kg/day for nursing infants less than 1 year old to 0.59 μg/kg/day for children ages 1 to 6 years old (Table 13).

Table 13. Potential Acute and Chronic Dietary Exposure to Propargite for Selected Population Subgroups

Population Subgroup	Exposure Dosage (µg/kg/day)	
	Acute[a]	Chronic[b]
U.S. Population	4.37	0.18
Western Region	4.34	0.19
Nursing Infants (< 1 yr)	4.08	0.07
Non-nursing Infants (< 1 yr)	6.25	0.28
Children (1-6 yrs)	6.81	0.59
Children (7-12 yrs)	3.24	0.30
Females (13+ yrs/pregnant/not nursing)	1.66	0.16
Females (13+ yrs/nursing)	1.68	0.16
Females (13-19 yrs/not pregnant or nursing)	1.80	0.13
Females (20+ yrs/not pregnant or nursing)	2.08	0.11
Males (13-19 yrs)	3.16	0.18
Males (20+ yrs)	3.97	0.12
Seniors (55+ yrs)	2.16	0.11
Workers (16+ yrs)	2.68	NA

[a] Based on 99.9th exposure percentile for each user-day population subgroups.

[b] Based on the annual average daily dosage for each population subgroups.

Drinking Water Assessment

Drinking Water Residues

From January 1993 through August 1998, 295 samples from surface water were examined for propargite in California and there were 15 detections ranging from 0.018 to 20 parts per billion (ppb) with a LOQ of 0.013 ppb (Starner, 2003). The estimated 95th percentile for the residues was 2.42 ppb and the mean residue level was 0.089 ppb. Most of the samples (7/12) with detected residues came from Orestimba Creek which is a tributary of the San Joaquin River. Residues were also detected in one or two samples from the Merced River (2), the Salt Slough (2) which is another tributary of the San Joaquin River, and the Colusa Basin Drain (1). It is uncertain if any of the surface water with detectable residues could be a source of drinking water. PDP analyzed 288 drinking water samples for propargite in 2001 from New York and California and found no detectable residues (USDA, 2003). Of these samples, 134 were from California with LOQs between 100 and 200 ppt.

Drinking Water Exposure

Although the PDP drinking water data is more realistic, the initial drinking water assessment was conducted using DPR's surface water residue data as a worse case scenario. If exposures were unacceptable with these data, then the PDP data would be used. Since there were enough surface water samples, the acute dietary assessment was conducted using a Monte

Carlo analysis. Based on the 99.9th percentile of user-day exposure for all specific population subgroups, the potential acute exposure to propargite in drinking water ranged from 0.34 µg/kg/day for workers 16 years and older to 2.34 µg/kg/day for non-nursing infants less than 1 year old (Table 14). The mean potential chronic drinking water exposure for all population subgroups ranged from 0.002 to 0.012 µg/kg/day (Table 14). The population subgroup with the highest potential chronic exposure to propargite in drinking water was also non-nursing infants less than 1 year old.

Table 14. Potential Acute and Chronic Drinking Water Exposure to Propargite for Selected Population Subgroups

Population Subgroup	Exposure Dosage (µg/kg/day)	
	Acute[a]	Chronic[a]
U.S. Population	0.42	0.003
Western Region	0.44	0.003
Nursing Infants (< 1 yr)	1.40	0.003
Non-nursing Infants (< 1 yr)	2.34	0.012
Children (1-6 yrs)	0.63	0.004
Children (7-12 yrs)	0.42	0.003
Females (13+ yrs/pregnant/not nursing)	0.46	0.002
Females (13+ yrs/nursing)	0.49	0.003
Females (13-19 yrs/not pregnant or nursing)	0.37	0.002
Females (20+ yrs/not pregnant or nursing)	0.38	0.002
Males (13-19 yrs)	0.42	0.002
Males (20+ yrs)	0.37	0.002
Seniors (55+ yrs)	0.34	0.002
Workers (16+ yrs)	0.38	NA

[a] Based on 99.9th exposure percentile for each user-day population subgroups.

[b] Based on the annual average daily dosage for each population subgroups.

Aggregate Exposure Assessment

The same dietary and drinking water residues used for the separate dietary and drinking water assessments were used for the acute (Tier 4) and chronic (Tier 3) aggregate assessment. The aggregate or combined drinking water and dietary exposure estimates are summarized in Table 15. The aggregate exposure to propargite in drinking water and food is not equal to the sum of the dietary and drinking water exposures because each of these estimates is based on a distribution among consumers which changes as commodities or water are added or removed. Based on the 99.9th percentile of user-day exposure for all specific population subgroups, the potential combined acute exposure to propargite in drinking water and food ranged from 1.80 to 6.80 µg/kg/day. Children ages 1 to 6 years old had the highest potential acute aggregate exposure. The mean potential combined chronic exposure for all population subgroups ranged from 0.07 to 0.60 µg/kg/day. The population subgroup with the highest potential chronic aggregate exposure was also children ages 1 to 6 years old.

Table 15. Potential Acute and Chronic Aggregate Exposure to Propargite for Selected Population Subgroups

Population Subgroup	Exposure Dosage (µg/kg/day)	
	Acute[a]	Chronic[b]
U.S. Population	4.36	0.18
Western Region	4.29	0.20
Nursing Infants (< 1 yr)	4.08	0.07
Non-nursing Infants (< 1 yr)	6.22	0.29
Children (1-6 yrs)	6.80	0.60
Children (7-12 yrs)	3.24	0.30
Females (13+ yrs/pregnant/not nursing)	1.70	0.16
Females (13+ yrs/nursing)	1.80	0.16
Females (13-19 yrs/not pregnant or nursing)	1.82	0.14
Females (20+ yrs/not pregnant or nursing)	2.09	0.11
Males (13-19 yrs)	3.16	0.18
Males (20+ yrs)	3.02	0.12
Seniors (55+ yrs)	2.14	0.11
Workers (16+ yrs)	2.73	NA

[a] Based on 99.9th exposure percentile for each user-day population subgroups.

[b] Based on the annual average daily dosage for each population subgroups.

C. RISK CHARACTERIZATION

The risk for non-oncogenic human health effects is expressed as a margin of exposure (MOE). The MOE is the ratio of the NOEL from experimental animal studies to the human exposure dosage.

$$Margin\ of\ Exposure = \frac{NOEL}{Exposure\ Dosage}$$

Dietary Exposure

The acute MOEs for dietary exposure to propargite were calculated for the various population subgroups using the NOEL for acute toxicity (2.0 mg/kg) and the acute dietary exposure dosages (Table 16). With the Tier 4 analysis, the MOEs for acute toxicity at the 99.9th percentile ranged from 290 for children ages 1 to 6 years old to 1,200 for females 13 years and older that were pregnant or nursing. The chronic MOEs for dietary exposure were calculated using the NOEL for chronic toxicity (3.8 mg/kg/day) and the chronic dietary exposure dosages (Table 16). With the Tier 3 analysis, the chronic MOEs ranged from 6,300 to 51,000. Children ages 1 to 6 years old had the highest chronic dietary exposure.

Table 16. Estimated Margins of Exposure for Potential Acute and Chronic Dietary Exposure to Propargite in Selected Population Subgroups.

Population Subgroup	Margin of Exposure[a]	
	Acute	Chronic
U.S. Population	460	21,000
Western Region	460	19,000
Nursing Infants (< 1 yr)	490	51,000
Non-nursing Infants (< 1 yr)	320	13,000
Children (1-6 yrs)	290	6,300
Children (7-12 yrs)	620	13,000
Females (13+ yrs/pregnant/not nursing)	1,200	23,000
Females (13+ yrs/nursing)	1,200	23,000
Females (13-19 yrs/not pregnant or nursing)	1,100	28,000
Females (20+ yrs/not pregnant or nursing)	960	34,000
Males (13-19 yrs)	630	21,000
Males (20+ yrs)	670	30,000
Seniors (55+ yrs)	930	33,000
Workers (16+ yrs)	740	NA

[a] Margin of Exposure = NOEL / Exposure Dosage. Acute NOEL = 2.0 mg/kg (rabbits, anorexia and delayed ossification). Chronic NOEL = 3.8 mg/kg/day (rats, reduced body weights and food consumption). Exposure dosages from Table 13. Values rounded to two significant figures.

Drinking Water Exposure

The acute MOEs for drinking water exposure to propargite are summarized in Table 17. The acute MOEs for drinking water ranged from 850 for non-nursing infants less than one year old to 5,800 for seniors 55 years old and older. The MOEs for chronic drinking water exposure to propargite are also summarized in Table 17. The chronic MOEs for drinking water exposure ranged from 330,000 for non-nursing infants less than one year old to greater than 1,000,000 for all other population subgroups.

Aggregate Exposure

The MOEs for acute and chronic aggregate exposure to propargite were calculated for the various population subgroups using the same acute and chronic NOELs used with dietary and drinking water exposure (Table 18). The acute MOEs for aggregate exposure ranged from 290 for children ages 1 to 6 years old to 1,200 for pregnant, non-nursing females 13 years and older. The chronic MOEs for aggregate exposure ranged from 6,300 to 51,000. Children ages 1 to 6 years old had the highest aggregate exposure. The MOEs for aggregate exposure are essentially identical to the MOEs for dietary exposure indicating that nearly all of the exposure is coming from the diet.

Table 17. Estimated Margins of Exposure for Potential Acute and Chronic Drinking Water Exposure to Propargite for Selected Population Subgroups

Population Subgroup	Margin of Exposure[a]	
	Acute	Chronic
U.S. Population	4,800	>1,000,000
Western Region	4,600	>1,000,000
Nursing Infants (< 1 yr)	1,400	>1,000,000
Non-nursing Infants (< 1 yr)	850	330,000
Children (1-6 yrs)	3,200	>1,000,000
Children (7-12 yrs)	4,700	>1,000,000
Females (13+ yrs/pregnant/not nursing)	4,300	>1,000,000
Females (13+ yrs/nursing)	4,000	>1,000,000
Females (13-19 yrs/not pregnant or nursing)	5,400	>1,000,000
Females (20+ yrs/not pregnant or nursing)	5,200	>1,000,000
Males (13-19 yrs)	4,700	>1,000,000
Males (20+ yrs)	5,400	>1,000,000
Seniors (55+ yrs)	5,800	>1,000,000
Workers (16+ yrs)	5,300	NA

[a] Margin of Exposure = NOEL / Exposure Dosage. Acute NOEL = 2.0 mg/kg (rabbits, anorexia and delayed ossification). Chronic NOEL = 3.8 mg/kg/day (rats, reduced body weights and food consumption). Exposure dosages from Table 14. Values rounded to two significant figures.

Table 18. Estimated Margins of Exposure for Potential Acute and Chronic Aggregate Exposure to Propargite for Selected Population Subgroups

Population Subgroup	Margin of Exposure[a]	
	Acute	Chronic
U.S. Population	460	21,000
Western Region	470	19,000
Nursing Infants (< 1 yr)	490	51,000
Non-nursing Infants (< 1 yr)	320	13,000
Children (1-6 yrs)	290	6,300
Children (7-12 yrs)	620	13,000
Females (13+ yrs/pregnant/not nursing)	1,200	23,000
Females (13+ yrs/nursing)	1,100	23,000
Females (13-19 yrs/not pregnant or nursing)	1,100	28,000
Females (20+ yrs/not pregnant or nursing)	950	34,000
Males (13-19 yrs)	633	21,000
Males (20+ yrs)	660	30,000
Seniors (55+ yrs)	930	33,000
Workers (16+ yrs)	730	NA

[a] Margin of Exposure = NOEL / Exposure Dosage. Acute NOEL = 2.0 mg/kg (rabbits, anorexia and delayed ossification). Chronic NOEL = 3.8 mg/kg/day (rats, reduced body weights and food consumption). Exposure dosages from Table 15. Values rounded to two significant figures.

Oncogenicity

Using a linear approach, the risk for oncogenic effects was calculated by multiplying the oncogenic potency by the exposure dosage.

Oncogenic Risk = Oncogenic Potency x Exposure Dosage

With the linear approach, the oncogenic risk from dietary exposure was calculated using the estimated oncogenic potency (5.9×10^{-3} to 2.6×10^{-2} $(mg/kg/day)^{-1}$) and the chronic dietary exposure for the U.S. population. The estimated oncogenic risk from dietary exposure to propargite ranged from 1.1×10^{-6} to 4.7×10^{-6}. Using the same oncogenic potency and the population subgroup, the estimated oncogenic risk from exposure to propargite in drinking water ranged from 1.6×10^{-8} to 6.8×10^{-8}. When drinking water exposure was combined with dietary exposure, the estimated oncogenic risk was similar to that for dietary exposure alone, ranging from 1.1×10^{-6} to 4.8×10^{-6}.

IV. RISK APPRAISAL

Introduction

Risk assessment is the process used to evaluate the potential for human exposure and the likelihood that the adverse effects observed in toxicity studies with laboratory animals will occur in humans under the specific exposure conditions. Every risk assessment has inherent limitations on the application of existing data to estimate the potential risk to human health. Therefore, certain assumptions and extrapolations are incorporated into the hazard identification, dose-response assessment, and exposure assessment processes. These, in turn, result in uncertainty in the risk characterization which integrates all the information from the previous three processes. Qualitatively, risk assessments for all chemicals have similar uncertainties. However, the degree or magnitude of the uncertainty can vary depending on the availability and quality of the data, and the types of exposure scenarios being assessed. Specific areas of uncertainty associated with this risk assessment for propargite are delineated in the following discussion.

Hazard Identification

A rabbit developmental toxicity study was selected as the definitive study for evaluating acute toxicity of propargite in humans (Serota *et al.*, 1983). The critical NOEL for acute toxicity was 2 mg/kg/day based on anorexia in the does and delayed ossification in the fetuses. There is some uncertainty regarding both of these endpoints. The anorexia was observed at 6 mg/kg/day as early as day 2 of dosing and exhibited a dose-related trend by treatment day 4. The anorexia was supported by maternal body weight losses at the same dose level between treatment days 1 and 6. Although the anorexia could be the result of more than one dose, the onset of the anorexia was so early it was considered an acute effect. Although adipsia was first observed on day 3 at 6 mg/kg/day, it did not exhibit a dose-related trend until day 9 of dosing. For this reason, adipsia was considered the result of repeated dosing rather than an acute effect. It is also unclear if the delayed ossification of the skull in the fetuses was from more than one dose. Delayed ossification is generally considered secondary to maternal toxicity (Manson and Kang, 1989). DPR assumed that the delayed ossification in this study was secondary to the maternal body weight loss and anorexia. Since the onset of anorexia and maternal body weight loss was early enough to consider them acute effects, it was assumed that the delayed ossification was also an acute effect. However, if these endpoints had been considered the result of cumulative toxicity rather than acute toxicity, then a higher NOEL would have been used. The next lowest NOEL was 8 mg/kg/day in another rabbit developmental toxicity study in which fused sternebrae were observed in fetuses at 10 mg/kg/day (Schardein, 1989). Although the NOEL was higher in the more recent Schardein study, DPR considered both studies acceptable based on FIFRA guidelines and, therefore, could not dismiss the earlier findings. However, if DPR had selected the Schardein study as the definitive study for evaluating acute toxicity, the acute MOEs would be 4-fold higher than estimated.

A 2-year feeding study in rats was selected as the definitive study for evaluating chronic exposure to propargite (Trutter, 1991). A NOEL of 3.8 mg/kg/day was observed based on reductions in body weights (2-6%) and food consumption (2-5%) at 19.2 mg/kg/day. Although the reductions in body weights and food consumption were statistically significant at the LOEL, they were modest. However, there were other effects at the LOEL including a non-significant reduction in survival, a non-significant increase in ulcers and distended mucosal glands of the jejunum and a significant increase in sarcomas of the jejunum which resulted in greater importance being placed on these reductions in body weight and food consumption. This was the lowest chronic NOEL observed. The NOEL in this rat study is supported by a similar NOEL of 4 mg/kg/day that was observed in a 1-year feeding study in dogs (Atkinson, 1991). The NOEL in this study was based on reductions in body weight, changes in hematology values, increased relative liver weights and involution of the thymus. The reduction in the body weights in dogs was more pronounced at the LOEL (18-20%) than in the rat study. A lower chronic NOEL might have been observed in rabbits if they had been exposed to propargite on a long-term basis. Rabbits appear to be more sensitive than rats based on the lower NOELs observed in the two rabbit developmental toxicity studies conducted by Serota *et al.* (1983) and Schardein (1989) and the rabbit 21-day dermal toxicity study conducted by Bailey (1987). In all three rabbit studies, one of the most sensitive endpoints was body weight reductions. The body weight reduction in one of the rabbit developmental toxicity studies may be related to the anorexia and adipsia observed. The cause of the anorexia is not clear, but it is not related to palatability of the test compound since it was administered by gavage. Anorexia was not observed in the other rabbit developmental toxicity study, but abnormal defecation was. The anorexia and abnormal defecation could be related to gastrointestinal irritation since propargite is very irritating. Since propargite was given in a bolus in these studies it may be more irritating to the gut than if the same dose was administered in the diet. In the 21-day dermal toxicity study, the body weight reductions may be related to the severe dermal irritation. Mice appear to be the least sensitive to propargite of all the species tested with chronic exposure.

There was an increase in undifferentiated sarcomas of the jejunum in rats in the study conducted by Trutter (1991). The incidence showed a dose-related trend and was statistically significant from controls by pairwise comparison. This increase was considered toxicologically significant in the weight of evidence for the following reasons: 1) this tumor type is relatively rare in rats; 2) there was a shortening of time to tumor in males; 3) the tumor was determined to be the cause of death in the majority of male rats with it; 4) it was demonstrated in another study with the same strain without the propylene oxide stabilizer and 5) similar tumors were observed in a study with Wistar rats. Because the tumor was associated with ulceration and ectatic mucosal glands, there was some question if the tumors might be due to an increase in cell proliferation. In addition, all of the genotoxicity studies were negative except one marginally acceptable HPRT gene mutation assay with CHO cells. In this study, the propargite in the dosing solution appeared to have either broken down or reacted with the vehicle, DMSO. Other well-conducted HPRT gene mutation assays using either acetone and DMSO as the vehicle at similar concentrations to the positive study were negative. A few cell proliferation studies were conducted which showed a transient increase in cell proliferation at 800 ppm. However, it is unclear if a transient increase in cell proliferation is sufficient to cause tumors. Therefore, a health protective assumption was made that a genotoxic mechanism was responsible for the increase in tumors and a linearized multistage model was used to evaluate the oncogenicity of

propargite. If a threshold mechanism had been assumed, the NOEL for tumors and associated ulceration and ectatic mucosal glands would be the same as the chronic NOEL selected based on body weight and food consumption in the same study. Therefore, the MOEs for oncogenicity would be the same as the chronic MOEs. However, given the uncertainty regarding the mechanism for the oncogenicity a larger MOE (e.g., > 1000) would be recommended than for chronic toxicity.

Exposure Assessment

The dietary exposure assessment was based primarily on PDP monitoring data and tolerance levels when no monitoring data were available. Most of the samples from the PDP monitoring had no detectable residues. Therefore, the exposure estimates were based mostly on the LOQs and tolerances for commodities. Commodity contribution analysis for acute and chronic exposure suggested that milk, eggs, tea, hops, pork, chicken and beans contributed more than 5% to the total exposure estimate. The residues for eggs, tea, hops, pork and beans were based on the tolerance. There were no detectable residues in the PDP monitoring for milk and poultry. Therefore, these exposure estimates were based on the LOQ. Consequently, it is possible the actual residues in these commodities are lower than estimated, especially in those commodities where the tolerance was used.

In addition, the acute dietary exposure is probably overestimated because it was assumed that all the commodities for which point estimates were used contained residues of propargite on the same day at the highest residue level which is highly unlikely. However, these conservative assumptions for acute exposure are counterbalanced to some degree by the fact that residues were monitored on composite samples which tends to eliminate the extreme values that might be found on single serving pieces of fruit or vegetables.

Drinking water exposure was probably overestimated for people whose only source of drinking water is well water since no residues of propargite were found in well water monitored in California. Drinking water exposure may also be overestimated for those people whose source of drinking water is surface water because it is uncertain that propargite residues would remain after water purification. PDP did drinking water analyses for propargite in 2001 and found no detectable residues in 288 samples collected from New York and California. There were no detections and the LOQs ranged from 90 to 200 ppt. These data suggests that the drinking water exposure was overestimated based on the samples DPR collected from various surface water sources.

Risk Characterization

Generally, an MOE of at least 100 is considered sufficiently protective of human health when the NOEL for an adverse systemic effect is derived from an animal study. The MOE of 100 allows for humans being 10 times more sensitive than animals and for a 10-fold variation in sensitivity between the lower range of the normal distribution in the overall population and the

sensitive subgroup (Dourson *et al.*, 2002). The acute MOEs for dietary exposure at the 99.9th percentile were greater than 100 for all population subgroups. The acute MOEs for drinking water were all greater than 500. When combined with dietary exposure, the acute MOEs for aggregate exposure were still greater than 200 for all populations subgroups. The chronic MOEs for dietary exposure were greater than 1,000 for all population subgroups. The chronic MOEs from drinking water exposure were all greater than 100,000. After combination with the dietary exposure, the chronic MOEs for aggregate exposure were virtually the same as the chronic MOEs for dietary exposure alone.

An oncogenic risk level less than 10^{-6} is generally considered negligible. The estimated oncogenic risk from exposure to propargite in drinking water is less than the negligible risk level. On the other hand, the upper bound estimate of oncogenic risk from dietary exposure to propargite in the U.S. population was slightly greater than the negligible risk level at 4.7×10^{-6}. The upper bound estimate of oncogenic risk from combined exposure to propargite in water and food was even higher at 4.8×10^{-6}. However, the oncogenic risk from dietary exposure to propargite may have been exaggerated based on the possible overestimation of chronic dietary residues levels in various commodities, especially milk, eggs, tea, hops, pork, chicken and beans. Chronic residue estimates for these commodities were based either on ½ of the LOQ from PDP monitoring or ½ of the tolerance level. Since all these residue values were theoretical the actual residues could have been considerably lower. As discussed earlier under the Hazard Identification, the oncogenic risk may also have been overestimated if a threshold mechanism was responsible for the tumors in rats. In this case the NOEL for these tumors would be the same as the NOEL used for chronic effects and, therefore, the MOEs would be the same as the chronic MOEs.

U.S. EPA's Reregistration Eligibility Document for Propargite

U.S. EPA completed a Reregistration Eligibility Decision (RED) for propargite in September 2001 (U.S. EPA, 2001a) . U.S. EPA evaluated dietary, drinking water and occupational exposure to propargite using route-specific NOELs whenever possible. The discussion here will be limited to dietary and drinking water risk estimates derived by U.S. EPA. A discussion of U.S. EPA's occupational risk estimates will be discussed in the risk appraisal of the addendum addressing occupational exposure to propargite. U.S. EPA did not select a NOEL to evaluate acute dietary exposure for the general population because they did not consider there to be an acute toxicity endpoint that was relevant for this population. However, they did select a NOEL to evaluate acute dietary exposure for females 13-50 yrs of age based on an increased incidence of fused sternebrae in a rabbit developmental toxicity study at 10 mg/kg/day (Schardein, 1990). U.S. EPA made no reference to the other rabbit developmental toxicity study conducted by Serota *et al.* (1983), so it is unclear why they did not use it. It is possible they considered the effects in Serota *et al.* study to be equivocal, and since these were not observed in the more recent study conducted by Schardein, the effects were not considered treatment-related. DPR considered both studies acceptable based on FIFRA guidelines and, therefore, could not dismiss the earlier findings. Therefore, DPR selected the NOEL of 2 mg/kg/day from the Serota *et al.* study based on anorexia in the does and delayed ossification in the fetuses at 6 mg/kg/day. For chronic dietary and drinking water exposure, U.S. EPA selected the rat study conducted by

Trutter (1991) to evaluate chronic dietary exposure. This is the same study that DPR selected. They set the NOEL at 4 mg/kg/day based on decreased body weights and increased mortality in males at 19 mg/kg/day. These were roughly the same NOELs/LOELs selected by DPR after rounding with slightly different endpoints identified. DPR did not flag the increased mortality in males at 19 mg/kg/day because the reduction in survival was only significant by trend analysis and not by pairwise comparison with controls. In addition, DPR included a reduction in food consumption in the effects at the LOEL, but U.S. EPA did not. U.S. EPA classified propargite as a group B_2 carcinogen (probable human carcinogen) based on the jejunal tumors in rats (Trutter, 1991) and calculated a Q_1* value of 3.3×10^{-2} $(mg/kg/day)^{-1}$ using a quantal model. DPR used the same tumors and study to calculate the oncogenic potency of propargite using a linearized multistage model (Global 86). DPR's oncogenic potency estimate ranged from 5.9×10^{-3} $(mg/kg/day)^{-1}$ to 2.9×10^{-2} $(mg/kg/day)^{-1}$.

U.S. EPA estimated acute dietary exposure to propargite using PDP data and a Monte Carlo analysis. At the 99.9th percentile, the acute dietary exposure for this population subgroup ranged from 0.42 µg/kg/day for non-pregnant, non-nursing females 20 years and older to 3.00 µg/kg/day for non-nursing, pregnant females 13 years and older. These estimates were similar to the estimates DPR obtained for the 99.9th percentile using mostly PDP data and a Monte Carlo analysis were there were detected residues with more than 30 samples analyzed. U.S. EPA estimated the chronic dietary exposure to range from 0.004 µg/kg/day for non-pregnant, non-nursing females 13-19 years old and males 13-19 years old to 0.015 µg/kg/day for children 1 to 6 years old. DPR's chronic exposure estimates were higher by several fold. Although DPR and U.S. EPA used the same PDP data and percent crop treated values for many crops, there were some important differences. All of the major contributors identified in DPR's chronic exposure analysis (milk, eggs, tea, hops, pork, chicken and beans) had higher residue values than used by U.S. EPA. U.S. EPA did not use the PDP data for poultry and beef since it was not available at the time. They also did not use the milk data; however, this should have been available at the time the dietary assessment was performed. Instead they estimated residues in these animal commodities based on feeding studies. These estimated residues were significantly lower than the LOQs from the PDP monitoring in these commodities. U.S. EPA also used field trial data for bean, hops, and tea . These studies were not submitted to DPR, so DPR used ½ of the tolerance level for the chronic residue. However, the residue values for these commodities were fairly similar between U.S. EPA and DPR (beans - 0.09 vs. 0.10 ppm, hops - 14 vs. 15 ppm, tea - 4.03 vs. 5.0 ppm, respectively).

U.S. EPA estimated drinking water exposure from both ground and surface water in their RED for propargite using simulation models (SCI-GROW for ground water and PRZM-EXAMS for surface water) and limited monitoring data from the U.S. Geologic Survey National Water Quality Assessment in the Orestimba Creek Watershed in California during 1992 and 1993. They used Drinking Water Levels of Comparison (DWLOCs) to evaluate risk for drinking water. A DWLOC is the concentration of pesticide that is acceptable as an upper limit taking into consideration the aggregate exposure from food, water and residential uses. A DWLOC may vary between population subgroups depending on water consumption patterns and body weights. The acute DWLOC for feamles 13-50 years old was 2400 ppb. Acute DWLOCs were not calculated for other population subgroups because no relevant toxicological endpoint was identified for the general population. The DWLOCs for chronic exposure ranged from 400 to

1400 ppb. The cancer DWLOC was 0.71 ppb for propargite. The estimated environmental concentration (EEC) for acute, chronic and cancer exposure to propargite in ground water was 0.006 ppb based on modeling with SCI-GROW which was less the DWLOCs for acute, chronic and cancer exposure. Based on the modeling and the fate studies which suggest that propargite has a low potential to reach groundwater, U.S. EPA did not have a concern for human exposure to propargite for drinking water from ground water sources. DPR does not consider propargite to be a potential ground water contaminant and no residues were detected in well water monitored by DPR between 1989 and 1996. Therefore, no residues were assumed to be in ground water. U.S. EPA's EECs for acute and chronic exposure in surface water were estimated to be 34 and 8.7 ppb, respectively, which are the peak and average concentrations, respectively, derived using the PRZM-EXAMS model. For cancer risk estimates, U.S. EPA used an EEC of 4.8 ppb, although it was not clear what assumptions were made to derive this slightly lower value. The peak value was similar to what DPR used (20 ppb); however, the chronic value was significantly higher than DPR's (0.089). The acute and chronic EECs for surface water were less than their respective DWLOCs. The cancer EEC for surface water was higher than the cancer DWLOC; however, U.S. EPA suggested the modeling estimates and monitoring data upon which their assessment was based was conservative. The registrant agreed to add label statements to prohibit ground application of propargite within 50 ft of aquatic areas and air application within 75 ft of aquatic areas. The registrant also agreed to conduct drinking water monitoring to confirm the Agency's belief that the drinking water exposures will not exceed the level of concern. A maximum contaminant level (MCL) has not been established for propargite in water (U.S. EPA, 2003).

As part of the Food Quality Protection Act (FQPA), U.S. EPA evaluated the developmental and reproductive toxicity studies for propargite and recommended the 10X uncertainty factor be reduced to 1X for several reasons: 1) developmental effects were only observed at maternally toxic doses; 2) exposure assessments did not underestimate potential dietary exposure for infants and children; 3) there is no residential use of propargite. DPR also concluded there was no evidence of increased pre- or post-natal sensitivity to propargite from the developmental and reproductive toxicity studies in rats and rabbits.

Issues Related to the Food Quality Protection Act

The Food Quality Protection Act of 1996 mandated U.S. EPA to "upgrade its risk assessment process as part of the tolerance setting procedures" (U.S. EPA, 1997a and b). The improvements to risk assessment were based on the recommendations from the 1993 National Academy of Sciences report, "Pesticides in the Diets of Infants and Children" (NAS, 1993). The Act required an explicit finding that tolerances are safe for children. U.S. EPA was required to use an extra 10-fold safety factor to take into account potential pre- and post-natal developmental toxicity and the completeness of the data unless U.S. EPA determined, based on reliable data, that a different margin would be safe. In addition, U.S. EPA must consider available information on: 1) aggregate exposure from all non-occupational sources; 2) effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity; 3) the effects of *in utero* exposure; and 4) the potential for endocrine disrupting effects.

Prenatal and Postnatal Sensitivity

Four developmental toxicity studies (2 with rats and 2 with rabbits) were available for propargite. All four studies were acceptable based on FIFRA guidelines. Fetal effects included increased abortions, increased resorptions, reduced fetal viability, delayed ossification, malaligned or fused sternebrae, hydrocephaly and reduced body weights. The lowest developmental NOEL in an acceptable study was equal to or greater than 2.0 mg/kg/day based on delayed ossification of the skull in rabbits. There was no evidence of increased prenatal sensitivity to propargite in any of these studies since the developmental NOELs were equal to or greater than the maternal NOELs. Two reproductive toxicity studies in rats were available for propargite, the main study and an ancillary cross-fostering study. The main study was found acceptable to DPR based on FIFRA guidelines. The primary effect observed in pups was reduced body weights. The pup NOEL was the same as parental NOEL, 80 ppm (4 mg/kg/day), suggesting there is no increased postnatal sensitivity to propargite. Based on both the developmental and reproductive toxicity studies, DPR concluded there is no increased susceptibility in infants and children to propargite.

Endocrine Effects

The Food Quality Protection Act (FQPA) of 1996 required U.S. EPA to develop a screening program to determine the endocrine disruption potential of pesticides. In 1997, the Risk Assessment Forum of the U.S. EPA published a report that reviewed the current state of science relative to environmental endocrine disruption (U.S. EPA, 1997c). U.S. EPA formed the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) to develop a strategy for screening and testing of pesticides for their potential to produce endocrine disruption. The EDSTAC members include various stakeholders and scientific experts. This screening and testing process is expected to be implemented by August of 1999 as required by FQPA.

Environmental chemicals can interact with the endocrine system, resulting in cancer, reproductive and/or developmental anomalies (EDSTAC, 1998). It may produce these effects by affecting hormonal production and synthesis, binding directly to hormone receptors or interfering with the breakdown of hormones (U.S. EPA, 1997c). The interim science policy stated in U.S. EPA's 1997 report is that "*the Agency does not consider endocrine disruption to be an adverse endpoint per se, but rather to be a mode or mechanism of action leading to other outcomes*. There were no adverse effects in laboratory animals exposed to propargite that appear to be related to endocrine disruption.

Cumulative Toxicity

Cumulative toxicity is not anticipated with propargite since it is the only organosulfur pesticide used on food and it is not expected to share any common mechanism of toxicity with any other pesticides.

Aggregate Exposure

Combined dietary and drinking water exposure has been addressed in this document. Combined dietary, drinking water and occupational exposure in workers will be addressed in an addendum to this document which addresses occupational exposure. Combined exposure in the general population to propargite in the diet, drinking water and ambient air will be addressed in this addendum if air monitoring data are available at that time. Otherwise, the exposure to propargite in ambient air will be addressed in a separate document when air monitoring data become available.

V. TOLERANCE ASSESSMENT

A. INTRODUCTION

U.S. EPA

U.S. EPA is responsible under the Federal Food, Drug, and Cosmetic Act (FFDCA) for setting tolerances for pesticide residues in RACs (Section 408 of FFDCA) and processed commodities (Section 409 of FFDCA). A tolerance is the legal maximum residue concentration of a pesticide which is allowed on a raw agricultural commodity or processed food. The tolerances are established at levels necessary for the maximum application rate and frequency, and not expected to produce deleterious health effects in humans from chronic dietary exposure (U.S. EPA, 1991). The data requirements for tolerances include: (1) residue chemistry, (2) environmental fate, (3) toxicology, (4) product performance such as efficacy, and (5) product chemistry (Code of Federal Regulations, 1996). The field studies must reflect the proposed use with respect to the rate and mode of application, number and timing of applications and formulations proposed (U.S. EPA, 1982).

In 1996, the Food Quality Protection Act (FQPA) amended the overall regulation of pesticide residues under FIFRA and FFDCA (U.S. EPA, 1997a and b). One major change was the removal of the Delaney Clause that prohibited residues of cancer-causing pesticides in processed foods. The tolerances must be health-based and the same standards are used to establish tolerances for both the RACs and their processed forms. FQPA required an explicit finding that tolerances are safe for children. U.S. EPA was required to use an extra 10-fold safety factor to take into account potential pre- and post-natal developmental toxicity and the completeness of the data unless U.S. EPA determined, based on reliable data, that a different margin would be safe. In addition, the evaluations of the tolerance must take into account: (1) aggregate exposure from all non-occupational sources, (2) effects from cumulative exposure to the pesticide and other substances with common mechanisms of toxicity, (3) effects of *in utero* exposure; and (4) potential for endocrine disrupting effects.

Under FQPA, U.S. EPA is also required to reassess all existing tolerances and exemptions from tolerances for both active and inert ingredients by 2006 (U.S. EPA, 1997d). Previously, U.S. EPA reassessed tolerances as part of its reregistration and Special Review processes. In the evaluation of tolerances, the U.S. EPA uses a tiered approach and the assessment includes all label-use commodities.

California

In California, U.S. EPA established tolerances are evaluated under the mandate of Assembly Bill 2161, generally referred to as the Food Safety Act (Bronzan and Jones, 1989).

The Act requires DPR to conduct an assessment of dietary risks associated with the consumption of produce and processed food treated with pesticides. In these assessments, the tolerance for each specific commodity is evaluated individually and is discussed in the following sections. For a pesticide registered for use on a large number of commodities, tolerance assessments are conducted for only a group of selected fruits and vegetables. Generally, commodities are selected from all the uses based on the potential for high levels of exposure. For a number of RACs, only the tolerances for the commodities on FDA's list of the 20 most frequently consumed fruits and vegetables consumed were examined. For propargite, the tolerances for the following commodities were evaluated: oranges (5.0 ppm), grapes (5.0 ppm), grapefruit (5.0 ppm), nectarines (4.0 ppm), milk (0.08 pp, except milk fat - 2.0 ppm), lemons (5.0 ppm), mint (50.0 ppm), tea (10.0 ppm), potatoes (0.1 ppm), poultry (0.1 ppm), dried beans (0.2 ppm), corn (0.1 ppm), pork (0.1 ppm), hops (15.0 ppm), eggs (0.1 ppm), and peanuts (0.1 ppm). These commodities were selected because of either their high consumption (oranges, grapes, milk, potatoes, poultry, beans, corn, pork, eggs and peanuts) and/or high tolerance (oranges, grapes, grapefruit, nectarines, lemons, mint, tea and hops).

B. ACUTE EXPOSURE

An acute exposure assessment is conducted for each individual label-approved commodity at the tolerance. The DEEM™ Acute Analysis software program and the 1994-98 USDA CSFII data were used in this assessment. The acute tolerance assessment does not routinely address multiple commodities at the tolerance levels since the probability of consuming multiple commodities at the tolerance decreases as the number of commodities included in the assessment increases. The 95th percentile of user-day exposures for all specific population subgroups was used in evaluating the margins of exposure for the various population subgroups.

The acute MOEs for the 16 commodities analyzed are summarized in Table 19. For a few commodities (mint, hops), there was no consumption reported in the 1994-98 USDA CSFII data for nursing and/or non-nursing infants less than 1 year old. There was also low consumption of some commodities by infants or pregnant or nursing females. When there were less than 25 user-days, the exposure estimates were considered so unreliable they were not reported. When there were more than 25 user-days, but less than 100 user-days for some population subgroups, the MOEs were reported, but flagged. These MOEs were considered less accurate estimates due to the small number of user-days.

The MOEs were less than 100 for all population subgroups for oranges and grapefruit. In addition, the MOEs were less than 100 for all the population groups, except males 13-19 years old, for grapes. For nectarines, the MOEs were less than 100 for all population subgroups except males and females (non-pregnant, non-nursing) 20 years and older and seniors 55 years and older. The MOEs for milk and lemons were all greater than 100, but less than 500 for some population subgroups. Consequently, the chronic exposure dosages for these population subgroups were added back in to the exposure estimated for each commodity to see if this background exposure increased the exposure estimates sufficiently to reduce the MOEs to less

than 100. In fact, the chronic exposure was only 1 to 15% of the acute exposure for the commodities in question and, therefore, did not result in a significant reduction in the MOEs. In no case were the MOEs reduced to less than 100 with the addition of the background residue levels. The MOEs for the remaining commodities (mint, tea, potatoes, poultry, beans, corn, pork, hops, eggs and peanuts) were all greater than 500. In conclusion, the tolerance levels for oranges, grapes, grapefruit and nectarines all appear to be too high based on their consumption levels in all or some population subgroups. This is not surprising for such high consumption commodities such as oranges and grapes, but it is more of a surprise for grapefruit and nectarines that have a low consumption. If the exposure estimates for grapefruit and nectarines were based on per capita consumption rather than per user consumption, the MOEs would be greater than 100.

C. CHRONIC EXPOSURE

A chronic exposure assessment using residues equal to the established tolerances for individual or combinations of commodities has not been conducted because it is highly improbable that an individual would chronically consume single or multiple commodities with pesticide residues at the tolerance levels. This conclusion is supported by data from both federal and DPR (formerly CDFA) pesticide monitoring programs which indicate that less than one percent of all sampled commodities have residue levels at or above the established tolerance (DPR, 1994-2002).

Table 19. Margins of Exposure for Acute Dietary Exposure to Tolerance Levels of Propargite on Selected Raw Agricultural Commodities[a]

Population Subgroup	Oranges	Grapefruit	Grapes	Nectarines	Milk
U.S. Population	16	64	74	77	470
Western Region	16	58	32	61	440
Nursing Infants (<1 yr)	10	LC	29	LC	650
Non-Nursing Infants (<1 yr)	10	LC	27	LC	180
Children (1-6 yrs)	8	44	12	41*	190
Children (7-12 yrs)	15	54*	38	LC	410
Females (13+ yrs/P/NN)	26*	LC	73*	LC	610
Females (13+ yrs/N)	24*	LC	91*	LC	740*
Females (13-19 yrs/NP/NN)	18	59*	51	LC	770
Females (20+ yrs/NP/NN)	26	76	38	134*	1,200
Males (13-19 yrs)	16	LC	103	LC	620
Males (20+ yrs)	25	64	45	113*	1,100
Seniors (55+ yrs)	38	87	45	120*	1,300

a Based on 95th exposure percentile for all user-day population subgroups. Values rounded to two significant figures.

* The margin of exposure (MOE) at the 95th percentile may not be reliable since consumption is based on less than 100 user-days.

LC There were less than 25 user-days for this population subgroup in the 1994-98 USDA Continuing Survey of Food Intakes by Individuals (CSFII), so MOE was not considered reliable.

P Pregnant

NN Not nursing

N Nursing

NP Not pregnant

Table 19 (cont.). Margins of Exposure for Acute Dietary Exposure to Tolerance Levels of Propargite on Selected Raw Agricultural Commodities[a]

Population Subgroup	Lemons	Mint	Tea	Potatoes	Poultry
U.S. Population	640	1,000	2,900	4,000	4,300
Western Region	620	570	2,800	3,800	4,300
Nursing Infants (<1 yr)	LC	NC	LC	2,500	2,300*
Non-Nursing Infants (<1 yr)	720*	LC	LC	1,800	2,300
Children (1-6 yrs)	260	690	1,600	2,000	2,500
Children (7-12 yrs)	420	790	2,700	3,000	3,500
Females (13+ yrs/P/NN)	480*	NC	3,200*	6,000*	4,900*
Females (13+ yrs/N)	630*	LC	LC	4,500*	6,400*
Females (13-19 yrs/NP/NN)	440	1,700*	3,100	4,500	5,600
Females (20+ yrs/NP/NN)	820	2,700	3,100	5,500	6,100
Males (13-19 yrs)	480	530*	2,700	3,400	4,000
Males (20+ yrs)	780	2,800	3,000	4,700	5,100
Seniors (55+ yrs)	1,200	2,900	3,800	5,500	6,700

a Based on 95th exposure percentile for all user-day population subgroups. Values rounded to two significant figures.

* The margin of exposure (MOE) at the 95th percentile may not be reliable since consumption is based on less than 100 user-days.

LC There were less than 25 user-days for this population subgroup in the 1994-98 USDA Continuing Survey of Food Intakes by Individuals (CSFII), so the MOE was not considered reliable.

NC There was no consumption of this commodity by this population subgroup in the 1994-98 USDA CSFII.

P Pregnant

NN Not nursing

N Nursing

NP Not pregnant

Table 19 (cont.). Margins of Exposure for Acute Dietary Exposure to Tolerance Levels of Propargite on Selected Raw Agricultural Commodities[a]

Population Subgroup	Beans	Corn	Pork	Hops	Eggs	Peanuts
U.S. Population	4,300	4,700	9,000	2,100	10,000	35,000
Western Region	3,800	4,800	9,700	2,000	8,900	34,000
Nursing Infants (<1 yr)	LC	3,400	4,400	NC	3,700	15,000*
Non-Nursing Infants (<1 yr)	3,000*	1,800	4,500	NC	3,400	65,000
Children (1-6 yrs)	2,200	2,400	4,600	LC	3,900	12,000
Children (7-12 yrs)	3,500	3,400	7,300	NC	7,700	19,000
Females (13+ yrs/P/NN)	6,700*	5,800	15,000	NC	12,000*	55,000
Females (13+ yrs/N)	LC	6,600*	14,000*	LC	13,000*	33,000*
Females (13-19 yrs/NP/NN)	5,400	5,400	12,000	LC	13,000	55,000
Females (20+ yrs/NP/NN)	6,300	8,600	12,000	2,400	14,000	75,000
Males (13-19 yrs)	4,200	4,600	8,400	1,200*	11,000	37,000
Males (20+ yrs)	5,500	7,200	9,400	2,100	13,000	49,000
Seniors (55+ yrs)	6,100	9,900	12,000	2,800	14,000	66,000

a Based on 95th exposure percentile for all user-day population subgroups. Values rounded to two significant figures.

* The margin of exposure (MOE) at the 95th percentile may not be reliable since consumption is based on less than 100 user-days.

LC There were less than 25 user-days for this population subgroup in the 1994-98 USDA Continuing Survey of Food Intakes by Individuals (CSFII), so the MOE was not considered reliable.

NC There was no consumption of this commodity by this population subgroup in the 1994-98 USDA CSFII.

P Pregnant

NN Not nursing

N Nursing

NP Not pregnant

VI. REFERENCE DOSES/CONCENTRATIONS

The reference dose (RfD) or reference concentration (RfC) is the dose at which not adverse effects are expected to occur in humans. RfDs and RfCs were calculated for propargite for acute, seasonal and chronic exposures. Generally, the RfDs are calculated by dividing the NOELs by an uncertainty factor of 100 when the NOEL is from an animal study to account for interspecies and intraspecies variation in sensitivity. Based on the NOEL selected for evaluating acute dietary exposure, the RfD for acute exposure is 0.02 mg/kg/day based on anorexia in pregnant rabbits and delayed ossification in their fetuses. This acute RfD could be used for evaluating dietary exposure without adjustment for oral absorption since dietary exposure dosages are usually expressed as external dosages. For evaluating occupational exposure, the RfD will probably need to be converted to an absorbed dosage since DPR usually calculates the exposure dosages for workers as absorbed dosages. The oral absorption for propargite was approximately 40%. Therefore, the acute occupational RfD for propargite would be 8 μg/kg. This occupational RfD would be only protective for systemic effects with occupational exposure, not local effects such as dermal irritation, which is a major concern. A RfC can be calculated for evaluating acute inhalation exposure (ambient air) using the acute oral NOEL selected for evaluating dietary exposure. First, the oral NOEL is adjusted for oral absorption (40%). The adjusted oral NOEL is then converted to an equivalent human inhalation NOEL by dividing it by the respiratory rate for humans.

$$human\ inhalation\ NOEL\ (mg/m^3) \quad = \quad \frac{animal\ oral\ NOEL\ (mg/kg)}{respiratory\ rate_{human}}$$

Since children have the highest respiratory rate for humans relative to their body weight, their respiratory rate was used for humans. The resulting equivalent acute human inhalation NOEL was 1.4 mg/m^3, assuming a default respiratory rate of 0.59 m^3/kg/day for children. After dividing the equivalent human inhalation NOEL by an uncertainty factor of 100, the resultant acute RfC is 14 μg/m^3 (0.95 ppb). The RfC can be expressed in ppm by multiplying by the molecular volume and dividing by the molecular weight of propargite.

$$RfC\ (mg/m^3) \quad = \quad \frac{human\ inhalation\ NOEL\ (mg/m^3)}{uncertainty\ \ factor\ (e.g.,100)}$$

$$RfC\ (ppm) \quad = \quad RfC\ (mg/m^3)\ x\ \frac{M.Vol.(24.5L\ @\ 25^{c}C)}{M.Wt.(350g)}$$

To evaluate seasonal occupational exposure, the lowest systemic NOEL in an acceptable dermal toxicity was selected, 1.0 mg/kg/day, which was based on reduced body weights, changes in clinical chemistry and hematological values, and increased relative organ weights in rabbits (Bailey, 1987). The adjusted dermal NOEL for propargite was 0.17 mg/kg/day assuming the dermal absorption in animals was 17%. Therefore, the seasonal RfD for occupational exposure is 1.7 μg/kg/day based on the adjusted NOEL. The adjusted dermal NOEL could also be used to calculate a seasonal RfC by converting it to the equivalent human inhalation NOEL of 0.29

mg/kg/day. The seasonal RfC for evaluating ambient air exposure to propargite is 2.9 μg/kg/day (0.20 ppb).

Based on the oral NOEL selected for evaluating chronic dietary exposure, the chronic dietary RfD for propargite is 0.038 mg/kg/day. After adjusting for oral absorption (40%), the equivalent occupational RfD would be 0.015 mg/kg/day. This adjusted oral NOEL can be used to calculate a chronic inhalation RfC. The human equivalent inhalation NOEL is 2.6 mg/m^3/day. The resultant chronic RfC for propargite is 26 $\mu g/m^3$/day or 1.8 ppb.

VI. CONCLUSIONS

The risks for potential adverse human health effects with dietary and drinking water exposure to propargite were evaluated. The MOEs for acute dietary exposure to propargite were greater than 200 for all population subgroups based primarily on USDA's PDP monitoring data. The MOEs for chronic dietary exposure to propargite were greater than 5,000. The MOEs for acute exposure to propargite in drinking water were greater than 500 for all population subgroups based on DPR monitoring data for surface water in California. The MOEs for chronic drinking water exposure to propargite were greater than 100,000. When dietary and drinking water exposures were combined, the acute and chronic MOEs were still greater than 200 and 5,000, respectively, for all population subgroups. The upper bound estimate of oncogenic risk from dietary exposure to propargite in the U.S. population was slightly greater than the negligible risk level. The estimated oncogenic risk from exposure to propargite in drinking water was less than the negligible risk level of 10^{-6}. Addition of the drinking water exposure to dietary exposure, increased the upper bound estimate for oncogenic risk only slightly. The acute dietary MOEs based on the tolerance for propargite residues were greater than 100 for all population subgroups on various commodities, except for oranges, grapes, grapefruit and nectarines. The tolerance levels for these commodities should be reevaluated.

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APPENDICES

Appendix A - Oncogenicity Computer Model Printout

Appendix B - Dietary and Drinking Water Exposure Analysis Printouts

APPENDIX A

Oncogenicity Computer Model Printout

DATE: 03/26/2003 TIME: 08:58:33

GLOBAL 86 (MAY 1986)

BY RICHARD B. HOWE AND CYNTHIA VAN LANDINGHAM

CLEMENT ASSOCIATES
1201 GAINES STREET
RUSTON, LA 71270
(318) 255-4800

Propargite, Jejunum Sarcomes, Male Rats at Risk

POLYNOMIAL DEGREE SELECTED BY PROGRAM, (POLY-DEGREE=0)
MONTE CARLO TEST USED IN SELECTION

GROUP	DOSE	#RESPONSES OBSERVED/#ANIMALS	#RESPONSES PREDICTED
1	.000000	0/ 44	.00
2	.700000	0/ 47	.14
3	1.20000	0/ 44	.37
4	5.80000	11/ 46	8.26
5	11.8000	24/ 46	25.72

CHI-SQUARE GOODNESS OF FIT STATISTIC IS 1.8806

P-VALUE FOR THE MONTE CARLO TEST IS .2250000000

FORM OF PROBABILITY FUNCTION:
P(DOSE) = 1 - exp(-Q0 - Q1 * D - Q2 * D^2)

MAXIMUM LIKELIHOOD ESTIMATES OF DOSE COEFFICIENTS

Q(0) = .000000000000

Q(1) = .000000000000
Q(2) = 5.881026713745E-03

MAXIMUM VALUE OF THE LOG-LIKELIHOOD IS -58.2966168242

CALCULATIONS ARE BASED UPON EXTRA RISK
LINEARIZED MULTISTAGE CONFIDENCE LIMITS
****

RISK	MLE DOSE	LOWER BOUND ON DOSE	UPPER BOUND ON RISK	CONFIDENCE LIMIT SIZE
.10000	4.2327	6.0067	7.15532E-02	90.0
		4.0901	.10330	95.0
		3.1526	.13191	97.5
		2.4583	.16591	99.0
1.00000E-02	1.3073	.57298	2.26690E-02	90.0
		.39016	3.31142E-02	95.0
		.30072	4.27489E-02	97.5
		.23449	5.44885E-02	99.0
1.00000E-03	.41246	5.70399E-02	7.20860E-03	90.0
		3.88396E-02	1.05687E-02	95.0
		2.99367E-02	1.36901E-02	97.5
		2.33435E-02	1.75226E-02	99.0
1.00000E-04	.13040	5.70142E-03	2.28469E-03	90.0
		3.88221E-03	3.35350E-03	95.0
		2.99232E-03	4.34862E-03	97.5
		2.33330E-03	5.57342E-03	99.0
1.00000E-05	4.12358E-02	5.70116E-04	7.23030E-04	90.0
		3.88203E-04	1.06166E-03	95.0
		2.99219E-04	1.37717E-03	97.5
		2.33320E-04	1.76580E-03	99.0
1.00000E-06	1.30399E-02	5.70114E-05	2.28698E-04	90.0
		3.88202E-05	3.35849E-04	95.0
		2.99217E-05	4.35705E-04	97.5
		2.33319E-05	5.58731E-04	99.0

1.00000E-07	4.12357E-03	5.70113E-06	7.23263E-05	90.0
		3.88201E-06	1.06217E-04	95.0
		2.99217E-06	1.37802E-04	97.5
		2.33319E-06	1.76720E-04	99.0
1.00000E-08	1.30399E-03	5.70114E-07	2.28722E-05	90.0
		3.88201E-07	3.35899E-05	95.0
		2.99218E-07	4.35790E-05	97.5
		2.33319E-07	5.58871E-05	99.0

END OF LINEARIZED MULTISTAGE CONFIDENCE LIMITS

****

GLOBAL 86 LOWER CONFIDENCE LIMITS ON DOSE FOR FIXED RISK

****

RISK	MLE DOSE	LOWER BOUND ON DOSE	CONFIDENCE LIMIT SIZE	COEFFICIENTS FOR CONFIDENCE LIMIT
1.00000E-06	1.30399E-02	3.88200E-05	95.0%	Q(0) = .00000
				Q(1) = 2.57598E-02
				Q(2) = 3.12908E-03

GLOBAL 86 UPPER CONFIDENCE LIMITS ON RISK FOR FIXED DOSE

****

DOSE	MLE RISK	UPPER BOUND ON RISK	CONFIDENCE LIMIT SIZE	COEFFICIENTS FOR CONFIDENCE LIMIT
1.0000	5.86377E-03	2.85135E-02	95.0%	Q(0) = .00000
				Q(1) = 2.57160E-02
				Q(2) = 3.21193E-03

NORMAL COMPLETION!

APPENDIX B

Dietary and Drinking Water Exposure Analysis Printouts

California Department of Pesticide Regulation Ver. 7.81
DEEM Acute analysis for PROPARGITE
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Acute.RS7
Analysis Date 11-03-2003 Residue file dated: 11-03-2003/14:45:59/14
Reference dose: aRfD = 0.08 mg/kg bw/day NOEL = 2 mg/kg bw/day

RDL indices and parameters for Monte Carlo Analysis:

Index #	Dist Code	Parameter #1	Param #2	Param #3	Comment
1	6	PropGR9600.rdf			
2	6	PropNE0001.rdf			
3	6	PropRA9600.rdf			

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	Adj.Factors #2	RDL Ind	Comment
13	O	Grapes	0.720000	1.000	1.000	1	PDP CA
		Full comment: PDP CA grapes RDF					
14	O	Grapes-raisins	0.720000	4.300	1.000	3	PDP CA
		Full comment: PDP CA grapes RDF w/ different PCT					
15	O	Grapes-juice	0.020000	1.000	1.000		PDP 98
		Full comment: PDP 98-99 grape juice CA LOQ					
22	10	Grapefruit-peeled fruit	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
23	10	Grapefruit-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
26	10	Lemons-peeled fruit	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
27	10	Lemons-peel	5.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
28	10	Lemons-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
30	10	Limes-peeled fruit	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
31	10	Limes-peel	5.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
32	10	Limes-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
33	10	Oranges-juice-concentrate	0.020000	3.720	1.000		PDP 97
		Full comment: PDP 97-98 orange juice LOQ					
34	10	Oranges-peeled fruit	0.020000	1.000	1.000		PDP 96
		Full comment: PDP 96, 00-01 orange CA LOQ					
35	10	Oranges-peel	5.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
36	10	Oranges-juice	0.020000	1.000	1.000		PDP 97
		Full comment: PDP 97-98 orange juice LOQ					
38	10	Tangerines	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
39	10	Tangerines-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
40	14	Almonds	0.100000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
48	14	Walnuts	0.100000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
64	12	Nectarines	1.200000	1.000	1.000	2	PDP CA
		Full comment: PDP CA nectarines RDF					
113	O	Tea	10.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
125	O	Hops	15.000000	1.000	1.000		U.S. E

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   Full comment: U.S. EPA tolerance
195 O    Grapes-leaves                    0.720000   1.000  1.000   1  PDP CA
   Full comment: PDP CA grapes RDF
207 1C   Potatoes/white-whole              0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
208 1C   Potatoes/white-unspecified        0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
209 1C   Potatoes/white-peeled             0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
210 1C   Potatoes/white-dry                0.020000   6.500  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
211 1C   Potatoes/white-peel only          0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
218 1CD  Sweet potatoes (incl yams)        0.020000   1.000  1.000      PDP CA
   Full comment: PDP CA sweet potato data
227 6C   Beans-dry-great northern          0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
228 6C   Beans-dry-kidney                  0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
229 6C   Beans-dry-lima                    0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
230 6C   Beans-dry-navy (pea)              0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
231 6C   Beans-dry-other                   0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
232 6C   Beans-dry-pinto                   0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
237 15   Corn/pop                          0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
238 15   Corn/sweet                        0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn data
244 6C   Mung beans (sprouts)              0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
249 6C   Beans-dry-broadbeans              0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
251 6C   Beans-dry-pigeon beans            0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
256 O    Beans-dry-hyacinth                0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
258 6C   Beans-dry-blackeye peas/cowpea    0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
259 6C   Beans-dry-garbanzo/chick pea      0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
266 15   Corn grain-endosperm              0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
267 15   Corn grain-bran                   0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
268 15   Corn grain/sugar/hfcs             0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
275 15   Sorghum (including milo)         10.000000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
289 15   Corn grain-oil                    0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
290 O    Cottonseed-oil                    0.050000   1.000  1.000      Field
   Full comment: Field trial data
291 O    Cottonseed-meal                   0.050000   1.000  1.000      Field
   Full comment: Field trial data
293 O    Peanuts-oil                       0.013000   1.000  1.000      PDP 20
   Full comment: PDP 2000 peanut butter LOQ
310 O    Peppermint                        2.730000   1.000  1.000      US. EP
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	Full comment: US. EPA field trial data					
311	O	Peppermint-oil	2.730000	1.000	1.000	US. EP
	Full comment: US. EPA field trial data					
312	O	Spearmint	4.730000	1.000	1.000	US. EP
	Full comment: US. EPA field trial data					
313	O	Spearmint-oil	4.730000	1.000	1.000	US. EP
	Full comment: US. EPA field trial data					
315	O	Grapes-wine and sherry	0.020000	1.000	1.000	PDP 98
	Full comment: PDP 98-99 grape juice CA LOQ					
318	D	Milk-nonfat solids	0.030000	1.000	1.000	PDP 96
	Full comment: PDP 96-98 whole milk CA LOQ					
319	D	Milk-fat solids	0.030000	1.000	1.000	PDP 96
	Full comment: PDP 96-98 whole milk CA LOQ					
320	D	Milk sugar (lactose)	0.030000	1.000	1.000	PDP 96
	Full comment: PDP 96-98 whole milk CA LOQ					
321	M	Beef-meat byproducts	0.009600	1.000	1.000	PDP 20
	Full comment: PDP 2001 beef liver LOQ					
322	M	Beef-other organ meats	0.009600	1.000	1.000	PDP 20
	Full comment: PDP 2001 beef liver LOQ					
323	M	Beef-dried	0.008600	1.920	1.000	PDP 20
	Full comment: PDP 2001 beef muscle LOQ					
324	M	Beef-fat w/o bones	0.024000	1.000	1.000	PDP 20
	Full comment: PDP 2001 beef adipose LOQ					
325	M	Beef-kidney	0.009600	1.000	1.000	PDP 20
	Full comment: PDP 2001 beef liver LOQ					
326	M	Beef-liver	0.009600	1.000	1.000	PDP 20
	Full comment: PDP 2001 beef liver LOQ					
327	M	Beef-lean (fat/free) w/o bones	0.008600	1.000	1.000	PDP 20
	Full comment: PDP 2001 beef muscle LOQ					
328	M	Goat-meat byproducts	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
329	M	Goat-other organ meats	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
330	M	Goat-fat w/o bone	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
331	M	Goat-kidney	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
332	M	Goat-liver	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
333	M	Goat-lean (fat/free) w/o bone	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
334	M	Horsemeat	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
336	M	Sheep-meat byproducts	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
337	M	Sheep-other organ meats	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
338	M	Sheep-fat w/o bone	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
339	M	Sheep-kidney	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
340	M	Sheep-liver	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
341	M	Sheep-lean (fat free) w/o bone	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
342	M	Pork-meat byproducts	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
343	M	Pork-other organ meats	0.100000	1.000	1.000	U.S. E
	Full comment: U.S. EPA tolerance					
344	M	Pork-fat w/o bone	0.100000	1.000	1.000	U.S. E

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   Full comment: U.S. EPA tolerance
345 M    Pork-kidney                          0.100000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
346 M    Pork-liver                           0.100000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
347 M    Pork-lean (fat free) w/o bone        0.100000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
355 P    Turkey-byproducts                    0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
356 P    Turkey-giblets (liver)               0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
357 P    Turkey--fat w/o bones                0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
358 P    Turkey- lean/fat free w/o bones      0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
360 P    Poultry-other-lean (fat free) w/     0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
361 P    Poultry-other-giblets(liver)         0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
362 P    Poultry-other-fat w/o bones          0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
363 P    Eggs-whole                           0.100000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
364 P    Eggs-white only                      0.100000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
365 P    Eggs-yolk only                       0.100000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
366 P    Chicken-byproducts                   0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
367 P    Chicken-giblets(liver)               0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
368 P    Chicken-fat w/o bones                0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
369 P    Chicken-lean/fat free w/o bones      0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
385 P    Chicken-giblets (excl. liver)        0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
388 15   Corn grain/sugar-molasses            0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
392 O    Grapes-juice-concentrate             0.020000   3.000  1.000      PDP 98
   Full comment: PDP 98-99 grape juice CA LOQ
398 D    Milk-based water                     0.030000   1.000  1.000      PDP 96
   Full comment: PDP 96-98 whole milk CA LOQ
403 O    Peanuts-butter                       0.013000   1.000  1.000      PDP 20
   Full comment: PDP 2000 peanut butter LOQ
418 2    Sweet potatos-leaves                 0.020000   1.000  1.000      PDP CA
   Full comment: PDP CA sweet potato data
420 10   Tangerines-juice-concentrate         0.020000   3.200  1.000      PDP or
   Full comment: PDP orange juice used as surrogate
424 M    Veal-fat w/o bones                   0.024000   1.000  1.000      PDP 20
   Full comment: PDP 2001 beef adipose LOQ
425 M    Veal-lean (fat free) w/o bones       0.008600   1.000  1.000      PDP 20
   Full comment: PDP 2001 beef muscle LOQ
426 M    Veal-kidney                          0.009600   1.000  1.000      PDP 20
   Full comment: PDP 2001 beef liver LOQ
427 M    Veal-liver                           0.009600   1.000  1.000      PDP 20
   Full comment: PDP 2001 beef liver LOQ
428 M    Veal-other organ meats               0.009600   1.000  1.000      PDP 20
   Full comment: PDP 2001 beef liver LOQ
429 M    Veal-dried                           0.008600   1.920  1.000      PDP 20
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   Full comment: PDP 2001 beef muscle LOQ
430 M    Veal-meat byproducts                0.009600   1.000  1.000      PDP 20
   Full comment: PDP 2001 beef liver LOQ
431 14   Walnut oil                          0.100000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
441 10   Grapefruit-juice-concentrate       0.020000   3.930  1.000      PDP or
   Full comment: PDP orange juice used as surrogate
442 10   Lemons-juice-concentrate            0.020000   5.700  1.000      PDP or
   Full comment: PDP orange juice used as surrogate
443 10   Limes-juice-concentrate             0.020000   3.000  1.000      PDP or
   Full comment: PDP orange juice used as surrogate
448 10   Grapefruit peel                     5.000000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
449 P    Turkey-other organ meats            0.033000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 poultry LOQ
940 O    Peanuts-hulled                      0.013000   1.000  1.000      PDP 20
   Full comment: PDP 2000 peanut butter LOQ
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DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""
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Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. Population:								
0.001474	1.84	1357	0.002540	3.17	787	0.004368	5.46	457
Western region:								
0.001538	1.92	1300	0.002590	3.24	772	0.004337	5.42	461
All infants:								
0.002111	2.64	947	0.004530	5.66	441	0.006177	7.72	323
Nursing infants (<1 yr old):								
0.000736	0.92	2716	0.001536	1.92	1302	0.004060	5.07	492
Non-nursing infants (<1 yr old):								
0.002526	3.16	791	0.004844	6.06	412	0.006247	7.81	320
Children 1-6 yrs:								
0.002914	3.64	686	0.004194	5.24	476	0.006809	8.51	293
Children 7-12 yrs:								
0.001507	1.88	1327	0.002190	2.74	913	0.003239	4.05	617
Females 13+ (preg/not nursing):								
0.001004	1.26	1991	0.001335	1.67	1498	0.001663	2.08	1202
Females 13+ (nursing):								
0.001001	1.25	1998	0.001209	1.51	1654	0.001685	2.11	1187
Females 13-19 (not preg or nursing):								
0.000937	1.17	2134	0.001303	1.63	1535	0.001805	2.26	1108
Females 20+ (not preg or nursing):								
0.000847	1.06	2359	0.001230	1.54	1625	0.002082	2.60	960
Females 13-50 yrs:								
0.000893	1.12	2240	0.001320	1.65	1515	0.002083	2.60	960
Males 13-19 yrs:								
0.001245	1.56	1605	0.001860	2.33	1074	0.003161	3.95	632
Males 20+ yrs:								
0.001039	1.30	1925	0.001722	2.15	1161	0.002975	3.72	672
Seniors 55+:								
0.000783	0.98	2553	0.001178	1.47	1698	0.002156	2.69	927
Custom demographics 1: Workers, 16+ yrs:								
0.000936	1.17	2137	0.001517	1.90	1318	0.002681	3.35	745

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Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

U.S. Population — Daily Exposure Analysis /a (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000524	0.000525
Standard Deviation	0.000507	0.000506
Margin of Exposure 2/	3,817	3,806
Percent of aRfD	0.65	0.66

Percent of Person-Days that are User-Days = 99.72%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000125	0.16	16,041	90.00	0.001081	1.35	1,850
20.00	0.000190	0.24	10,515	95.00	0.001475	1.84	1,355
30.00	0.000250	0.31	7,984	97.50	0.001913	2.39	1,045
40.00	0.000313	0.39	6,396	99.00	0.002541	3.18	787
50.00	0.000383	0.48	5,221	99.50	0.003034	3.79	659
60.00	0.000463	0.58	4,320	99.75	0.003528	4.41	566
70.00	0.000570	0.71	3,508	99.90	0.004370	5.46	457
80.00	0.000742	0.93	2,693				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000123	0.15	16,301	90.00	0.001079	1.35	1,853
20.00	0.000189	0.24	10,597	95.00	0.001474	1.84	1,357
30.00	0.000249	0.31	8,020	97.50	0.001911	2.39	1,046
40.00	0.000312	0.39	6,418	99.00	0.002540	3.17	787
50.00	0.000382	0.48	5,235	99.50	0.003031	3.79	659
60.00	0.000462	0.58	4,329	99.75	0.003525	4.41	567
70.00	0.000569	0.71	3,514	99.90	0.004368	5.46	457
80.00	0.000741	0.93	2,698				

a/ Analysis based on all two-day participant records in CSFII 1994-98 survey.
2/ Margin of Exposure = NOEL/ Dietary Exposure.

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Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Western region

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000548	0.000551
Standard Deviation	0.000526	0.000526
Margin of Exposure	3,646	3,629
Percent of aRfD	0.69	0.69

Percent of Person-Days that are User-Days = 99.54%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000124	0.16	16,088	90.00	0.001145	1.43	1,747
20.00	0.000197	0.25	10,177	95.00	0.001540	1.92	1,299
30.00	0.000262	0.33	7,627	97.50	0.002000	2.50	1,000
40.00	0.000328	0.41	6,090	99.00	0.002591	3.24	771
50.00	0.000400	0.50	5,002	99.50	0.003126	3.91	639
60.00	0.000485	0.61	4,119	99.75	0.003591	4.49	556
70.00	0.000599	0.75	3,340	99.90	0.004339	5.42	460
80.00	0.000791	0.99	2,528				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000121	0.15	16,483	90.00	0.001142	1.43	1,751
20.00	0.000194	0.24	10,314	95.00	0.001538	1.92	1,300
30.00	0.000260	0.33	7,682	97.50	0.001996	2.50	1,001
40.00	0.000327	0.41	6,115	99.00	0.002590	3.24	772
50.00	0.000398	0.50	5,026	99.50	0.003124	3.91	640
60.00	0.000483	0.60	4,140	99.75	0.003588	4.48	557
70.00	0.000597	0.75	3,351	99.90	0.004337	5.42	461
80.00	0.000789	0.99	2,535				

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Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

All infants

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000532	0.000606
Standard Deviation	0.000803	0.000830
Margin of Exposure	3,758	3,299
Percent of aRfD	0.67	0.76

Percent of Person-Days that are User-Days = 87.78%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000093	0.12	21,401	90.00	0.001286	1.61	1,555
20.00	0.000136	0.17	14,662	95.00	0.002283	2.85	876
30.00	0.000221	0.28	9,044	97.50	0.003214	4.02	622
40.00	0.000293	0.37	6,834	99.00	0.004784	5.98	418
50.00	0.000369	0.46	5,419	99.50	0.005484	6.86	364
60.00	0.000442	0.55	4,524	99.75	0.005727	7.16	349
70.00	0.000553	0.69	3,619	99.90	0.006185	7.73	323
80.00	0.000733	0.92	2,727				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.001134	1.42	1,763
20.00	0.000087	0.11	22,861	95.00	0.002111	2.64	947
30.00	0.000138	0.17	14,535	97.50	0.002990	3.74	668
40.00	0.000235	0.29	8,518	99.00	0.004530	5.66	441
50.00	0.000318	0.40	6,282	99.50	0.005355	6.69	373
60.00	0.000400	0.50	5,005	99.75	0.005712	7.14	350
70.00	0.000503	0.63	3,976	99.90	0.006177	7.72	323
80.00	0.000682	0.85	2,934				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Nursing infants (<1 yr old)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000172	0.000309
Standard Deviation	0.000354	0.000428
Margin of Exposure	11,635	6,476
Percent of aRfD	0.21	0.39

Percent of Person-Days that are User-Days = 55.66%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000024	0.03	82,667	90.00	0.000718	0.90	2,784
20.00	0.000061	0.08	32,658	95.00	0.000968	1.21	2,067
30.00	0.000089	0.11	22,542	97.50	0.001363	1.70	1,467
40.00	0.000130	0.16	15,367	99.00	0.002188	2.73	914
50.00	0.000179	0.22	11,164	99.50	0.002769	3.46	722
60.00	0.000246	0.31	8,129	99.75	0.003282	4.10	609
70.00	0.000322	0.40	6,216	99.90	0.004078	5.10	490
80.00	0.000458	0.57	4,365				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000477	0.60	4,191
20.00	0.000000	0.00	>1,000,000	95.00	0.000736	0.92	2,716
30.00	0.000000	0.00	>1,000,000	97.50	0.001096	1.37	1,824
40.00	0.000000	0.00	>1,000,000	99.00	0.001536	1.92	1,302
50.00	0.000025	0.03	81,100	99.50	0.002199	2.75	909
60.00	0.000083	0.10	24,061	99.75	0.002777	3.47	720
70.00	0.000156	0.20	12,816	99.90	0.004060	5.07	492
80.00	0.000276	0.35	7,238				

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DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Non-nursing infants (<1 yr old) Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000669	0.000669
Standard Deviation	0.000880	0.000880
Margin of Exposure	2,990	2,989
Percent of aRfD	0.84	0.84

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000111	0.14	17,961	90.00	0.001507	1.88	1,326
20.00	0.000171	0.21	11,687	95.00	0.002526	3.16	791
30.00	0.000263	0.33	7,618	97.50	0.003340	4.18	598
40.00	0.000337	0.42	5,941	99.00	0.004844	6.06	412
50.00	0.000402	0.50	4,970	99.50	0.005499	6.87	363
60.00	0.000480	0.60	4,167	99.75	0.005749	7.19	347
70.00	0.000597	0.75	3,347	99.90	0.006247	7.81	320
80.00	0.000796	1.00	2,511				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000111	0.14	17,973	90.00	0.001507	1.88	1,327
20.00	0.000171	0.21	11,696	95.00	0.002526	3.16	791
30.00	0.000262	0.33	7,622	97.50	0.003340	4.18	598
40.00	0.000337	0.42	5,942	99.00	0.004844	6.06	412
50.00	0.000402	0.50	4,971	99.50	0.005499	6.87	363
60.00	0.000480	0.60	4,168	99.75	0.005749	7.19	347
70.00	0.000597	0.75	3,348	99.90	0.006247	7.81	320
80.00	0.000796	1.00	2,512				

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DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Children 1-6 yrs

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.001391	0.001391
Standard Deviation	0.000841	0.000841
Margin of Exposure	1,438	1,437
Percent of aRfD	1.74	1.74

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000529	0.66	3,778	90.00	0.002413	3.02	828
20.00	0.000736	0.92	2,718	95.00	0.002914	3.64	686
30.00	0.000909	1.14	2,200	97.50	0.003418	4.27	585
40.00	0.001066	1.33	1,876	99.00	0.004194	5.24	476
50.00	0.001232	1.54	1,623	99.50	0.004895	6.12	408
60.00	0.001417	1.77	1,411	99.75	0.005579	6.97	358
70.00	0.001627	2.03	1,229	99.90	0.006809	8.51	293
80.00	0.001924	2.41	1,039				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000529	0.66	3,781	90.00	0.002413	3.02	828
20.00	0.000735	0.92	2,719	95.00	0.002914	3.64	686
30.00	0.000909	1.14	2,200	97.50	0.003418	4.27	585
40.00	0.001066	1.33	1,876	99.00	0.004194	5.24	476
50.00	0.001232	1.54	1,623	99.50	0.004895	6.12	408
60.00	0.001417	1.77	1,411	99.75	0.005579	6.97	358
70.00	0.001627	2.03	1,229	99.90	0.006809	8.51	293
80.00	0.001924	2.41	1,039				

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DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Children 7-12 yrs

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000744	0.000744
Standard Deviation	0.000429	0.000429
Margin of Exposure	2,687	2,687
Percent of aRfD	0.93	0.93

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000282	0.35	7,102	90.00	0.001274	1.59	1,569
20.00	0.000390	0.49	5,128	95.00	0.001507	1.88	1,327
30.00	0.000492	0.62	4,064	97.50	0.001769	2.21	1,130
40.00	0.000583	0.73	3,428	99.00	0.002190	2.74	913
50.00	0.000676	0.84	2,959	99.50	0.002408	3.01	830
60.00	0.000779	0.97	2,566	99.75	0.002856	3.57	700
70.00	0.000885	1.11	2,259	99.90	0.003239	4.05	617
80.00	0.001031	1.29	1,939				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000282	0.35	7,102	90.00	0.001274	1.59	1,569
20.00	0.000390	0.49	5,128	95.00	0.001507	1.88	1,327
30.00	0.000492	0.62	4,064	97.50	0.001769	2.21	1,130
40.00	0.000583	0.73	3,428	99.00	0.002190	2.74	913
50.00	0.000676	0.84	2,959	99.50	0.002408	3.01	830
60.00	0.000779	0.97	2,566	99.75	0.002856	3.57	700
70.00	0.000885	1.11	2,259	99.90	0.003239	4.05	617
80.00	0.001031	1.29	1,939				

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Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13+ (preg/not nursing)

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000447	0.000456
Standard Deviation	0.000305	0.000301
Margin of Exposure	4,477	4,386
Percent of aRfD	0.56	0.57

Percent of Person-Days that are User-Days = 97.96%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000109	0.14	18,272	90.00	0.000849	1.06	2,356
20.00	0.000208	0.26	9,612	95.00	0.001005	1.26	1,989
30.00	0.000256	0.32	7,822	97.50	0.001234	1.54	1,620
40.00	0.000308	0.38	6,496	99.00	0.001335	1.67	1,498
50.00	0.000380	0.48	5,261	99.50	0.001635	2.04	1,223
60.00	0.000510	0.64	3,924	99.75	0.001650	2.06	1,212
70.00	0.000583	0.73	3,430	99.90	0.001663	2.08	1,202
80.00	0.000660	0.83	3,029				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000097	0.12	20,688	90.00	0.000847	1.06	2,362
20.00	0.000201	0.25	9,960	95.00	0.001004	1.26	1,991
30.00	0.000247	0.31	8,083	97.50	0.001233	1.54	1,621
40.00	0.000306	0.38	6,537	99.00	0.001335	1.67	1,498
50.00	0.000373	0.47	5,367	99.50	0.001635	2.04	1,223
60.00	0.000472	0.59	4,233	99.75	0.001650	2.06	1,212
70.00	0.000579	0.72	3,456	99.90	0.001663	2.08	1,202
80.00	0.000659	0.82	3,035				

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DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13+ (nursing)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000477	0.000477
Standard Deviation	0.000265	0.000265
Margin of Exposure	4,188	4,188
Percent of aRfD	0.60	0.60

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000198	0.25	10,110	90.00	0.000821	1.03	2,437
20.00	0.000274	0.34	7,295	95.00	0.001001	1.25	1,998
30.00	0.000322	0.40	6,220	97.50	0.001022	1.28	1,956
40.00	0.000370	0.46	5,400	99.00	0.001209	1.51	1,654
50.00	0.000423	0.53	4,729	99.50	0.001356	1.70	1,474
60.00	0.000478	0.60	4,182	99.75	0.001365	1.71	1,465
70.00	0.000554	0.69	3,607	99.90	0.001685	2.11	1,187
80.00	0.000692	0.87	2,889				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000198	0.25	10,110	90.00	0.000821	1.03	2,437
20.00	0.000274	0.34	7,295	95.00	0.001001	1.25	1,998
30.00	0.000322	0.40	6,220	97.50	0.001022	1.28	1,956
40.00	0.000370	0.46	5,400	99.00	0.001209	1.51	1,654
50.00	0.000423	0.53	4,729	99.50	0.001356	1.70	1,474
60.00	0.000478	0.60	4,182	99.75	0.001365	1.71	1,465
70.00	0.000554	0.69	3,607	99.90	0.001685	2.11	1,187
80.00	0.000692	0.87	2,889				

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Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13-19 (not preg or nursing) Daily Exposure Analysis
(mg/kg body-weight/day)

	per Capita	per User
Mean	0.000390	0.000391
Standard Deviation	0.000279	0.000279
Margin of Exposure	5,126	5,116
Percent of aRfD	0.49	0.49

Percent of Person-Days that are User-Days = 99.80%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000097	0.12	20,554	90.00	0.000752	0.94	2,657
20.00	0.000159	0.20	12,587	95.00	0.000937	1.17	2,133
30.00	0.000214	0.27	9,329	97.50	0.001134	1.42	1,763
40.00	0.000270	0.34	7,404	99.00	0.001303	1.63	1,534
50.00	0.000329	0.41	6,082	99.50	0.001416	1.77	1,412
60.00	0.000401	0.50	4,990	99.75	0.001437	1.80	1,391
70.00	0.000478	0.60	4,185	99.90	0.001805	2.26	1,108
80.00	0.000579	0.72	3,452				

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000096	0.12	20,842	90.00	0.000752	0.94	2,660
20.00	0.000158	0.20	12,666	95.00	0.000937	1.17	2,134
30.00	0.000214	0.27	9,354	97.50	0.001134	1.42	1,764
40.00	0.000270	0.34	7,413	99.00	0.001303	1.63	1,535
50.00	0.000328	0.41	6,093	99.50	0.001416	1.77	1,412
60.00	0.000400	0.50	4,996	99.75	0.001437	1.80	1,391
70.00	0.000477	0.60	4,188	99.90	0.001805	2.26	1,108
80.00	0.000579	0.72	3,454				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 20+ (not preg or nursing) Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000354	0.000355
Standard Deviation	0.000261	0.000261
Margin of Exposure	5,641	5,634
Percent of aRfD	0.44	0.44

Percent of Person-Days that are User-Days = 99.86%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000103	0.13	19,424	90.00	0.000671	0.84	2,978
20.00	0.000151	0.19	13,209	95.00	0.000848	1.06	2,358
30.00	0.000198	0.25	10,118	97.50	0.001000	1.25	2,000
40.00	0.000245	0.31	8,163	99.00	0.001231	1.54	1,625
50.00	0.000297	0.37	6,723	99.50	0.001511	1.89	1,323
60.00	0.000357	0.45	5,609	99.75	0.001631	2.04	1,226
70.00	0.000421	0.53	4,751	99.90	0.002082	2.60	960
80.00	0.000510	0.64	3,924				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000102	0.13	19,522	90.00	0.000671	0.84	2,980
20.00	0.000151	0.19	13,264	95.00	0.000847	1.06	2,359
30.00	0.000197	0.25	10,143	97.50	0.001000	1.25	2,000
40.00	0.000245	0.31	8,176	99.00	0.001230	1.54	1,625
50.00	0.000297	0.37	6,734	99.50	0.001510	1.89	1,324
60.00	0.000356	0.45	5,616	99.75	0.001631	2.04	1,226
70.00	0.000421	0.53	4,754	99.90	0.002082	2.60	960
80.00	0.000509	0.64	3,927				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13-50 yrs

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000370	0.000370
Standard Deviation	0.000276	0.000276
Margin of Exposure	5,412	5,399
Percent of aRfD	0.46	0.46

Percent of Person-Days that are User-Days = 99.76%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000100	0.13	19,957	90.00	0.000720	0.90	2,777
20.00	0.000149	0.19	13,400	95.00	0.000893	1.12	2,238
30.00	0.000199	0.25	10,031	97.50	0.001065	1.33	1,877
40.00	0.000253	0.32	7,917	99.00	0.001320	1.65	1,514
50.00	0.000308	0.39	6,484	99.50	0.001504	1.88	1,329
60.00	0.000371	0.46	5,390	99.75	0.001703	2.13	1,174
70.00	0.000443	0.55	4,517	99.90	0.002083	2.60	960
80.00	0.000549	0.69	3,642				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000099	0.12	20,186	90.00	0.000720	0.90	2,779
20.00	0.000148	0.19	13,480	95.00	0.000893	1.12	2,240
30.00	0.000199	0.25	10,069	97.50	0.001065	1.33	1,878
40.00	0.000252	0.31	7,945	99.00	0.001320	1.65	1,515
50.00	0.000308	0.38	6,498	99.50	0.001504	1.88	1,329
60.00	0.000370	0.46	5,398	99.75	0.001703	2.13	1,174
70.00	0.000442	0.55	4,523	99.90	0.002083	2.60	960
80.00	0.000549	0.69	3,645				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Males 13-19 yrs

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000511	0.000511
Standard Deviation	0.000375	0.000375
Margin of Exposure	3,911	3,911
Percent of aRfD	0.64	0.64

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000148	0.19	13,506	90.00	0.000935	1.17	2,138
20.00	0.000232	0.29	8,632	95.00	0.001245	1.56	1,605
30.00	0.000294	0.37	6,803	97.50	0.001468	1.84	1,362
40.00	0.000360	0.45	5,548	99.00	0.001860	2.33	1,074
50.00	0.000426	0.53	4,699	99.50	0.002144	2.68	932
60.00	0.000507	0.63	3,947	99.75	0.002889	3.61	692
70.00	0.000600	0.75	3,335	99.90	0.003161	3.95	632
80.00	0.000742	0.93	2,696				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000148	0.19	13,506	90.00	0.000935	1.17	2,138
20.00	0.000232	0.29	8,632	95.00	0.001245	1.56	1,605
30.00	0.000294	0.37	6,803	97.50	0.001468	1.84	1,362
40.00	0.000360	0.45	5,548	99.00	0.001860	2.33	1,074
50.00	0.000426	0.53	4,699	99.50	0.002144	2.68	932
60.00	0.000507	0.63	3,947	99.75	0.002889	3.61	692
70.00	0.000600	0.75	3,335	99.90	0.003161	3.95	632
80.00	0.000742	0.93	2,696				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Males 20+ yrs

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000426	0.000427
Standard Deviation	0.000339	0.000339
Margin of Exposure	4,692	4,688
Percent of aRfD	0.53	0.53

Percent of Person-Days that are User-Days = 99.91%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000126	0.16	15,897	90.00	0.000795	0.99	2,514
20.00	0.000187	0.23	10,688	95.00	0.001039	1.30	1,925
30.00	0.000241	0.30	8,313	97.50	0.001298	1.62	1,540
40.00	0.000290	0.36	6,899	99.00	0.001722	2.15	1,161
50.00	0.000348	0.43	5,750	99.50	0.002150	2.69	930
60.00	0.000412	0.52	4,849	99.75	0.002548	3.18	785
70.00	0.000488	0.61	4,094	99.90	0.002975	3.72	672
80.00	0.000594	0.74	3,367				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000125	0.16	15,964	90.00	0.000795	0.99	2,515
20.00	0.000187	0.23	10,712	95.00	0.001039	1.30	1,925
30.00	0.000240	0.30	8,324	97.50	0.001298	1.62	1,541
40.00	0.000290	0.36	6,905	99.00	0.001722	2.15	1,161
50.00	0.000348	0.43	5,754	99.50	0.002149	2.69	930
60.00	0.000412	0.52	4,852	99.75	0.002548	3.18	785
70.00	0.000488	0.61	4,095	99.90	0.002975	3.72	672
80.00	0.000594	0.74	3,369				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Seniors 55+

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000355	0.000355
Standard Deviation	0.000242	0.000242
Margin of Exposure	5,629	5,626
Percent of aRfD	0.44	0.44

Percent of Person-Days that are User-Days = 99.95%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000118	0.15	17,012	90.00	0.000632	0.79	3,165
20.00	0.000172	0.22	11,604	95.00	0.000783	0.98	2,553
30.00	0.000217	0.27	9,213	97.50	0.000950	1.19	2,105
40.00	0.000261	0.33	7,657	99.00	0.001178	1.47	1,698
50.00	0.000307	0.38	6,522	99.50	0.001432	1.79	1,396
60.00	0.000357	0.45	5,595	99.75	0.001620	2.03	1,234
70.00	0.000422	0.53	4,743	99.90	0.002156	2.69	927
80.00	0.000498	0.62	4,017				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000117	0.15	17,048	90.00	0.000632	0.79	3,166
20.00	0.000172	0.22	11,617	95.00	0.000783	0.98	2,553
30.00	0.000217	0.27	9,221	97.50	0.000950	1.19	2,105
40.00	0.000261	0.33	7,660	99.00	0.001178	1.47	1,698
50.00	0.000307	0.38	6,524	99.50	0.001432	1.79	1,396
60.00	0.000357	0.45	5,596	99.75	0.001620	2.03	1,234
70.00	0.000422	0.53	4,744	99.90	0.002156	2.69	927
80.00	0.000498	0.62	4,017				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:16:53 Residue file dated: 11-03-2003/14:45:59/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Custom demographics 1: Workers, 16+ yrs
All Seasons
All Regions
Sex: M/F-all/
All Races
Age-Low: 16 yrs High: 99 yrs

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000393	0.000393
Standard Deviation	0.000306	0.000306
Margin of Exposure	5,093	5,086
Percent of aRfD	0.49	0.49

Percent of Person-Days that are User-Days = 99.87%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000112	0.14	17,894	90.00	0.000745	0.93	2,684
20.00	0.000168	0.21	11,904	95.00	0.000936	1.17	2,136
30.00	0.000219	0.27	9,120	97.50	0.001160	1.45	1,723
40.00	0.000268	0.34	7,458	99.00	0.001517	1.90	1,318
50.00	0.000323	0.40	6,190	99.50	0.001808	2.26	1,105
60.00	0.000387	0.48	5,168	99.75	0.002223	2.78	899
70.00	0.000458	0.57	4,366	99.90	0.002681	3.35	745
80.00	0.000558	0.70	3,586				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000111	0.14	18,017	90.00	0.000745	0.93	2,686
20.00	0.000167	0.21	11,945	95.00	0.000936	1.17	2,137
30.00	0.000219	0.27	9,140	97.50	0.001160	1.45	1,724
40.00	0.000268	0.33	7,469	99.00	0.001517	1.90	1,318
50.00	0.000323	0.40	6,198	99.50	0.001808	2.26	1,106
60.00	0.000387	0.48	5,173	99.75	0.002222	2.78	899
70.00	0.000458	0.57	4,370	99.90	0.002681	3.35	745
80.00	0.000557	0.70	3,588				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""
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Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. Population:								
0.000001	0.00	>1000000	0.000038	0.05	53323	0.000415	0.52	4817
Western region:								
0.000001	0.00	>1000000	0.000040	0.05	49435	0.000438	0.55	4567
All infants:								
0.000002	0.00	826196	0.000091	0.11	21973	0.002056	2.57	972
Nursing infants (<1 yr old):								
0.000001	0.00	>1000000	0.000014	0.02	145410	0.000941	1.18	2125
Non-nursing infants (<1 yr old):								
0.000003	0.00	605951	0.000139	0.17	14353	0.002338	2.92	855
Children 1-6 yrs:								
0.000002	0.00	>1000000	0.000047	0.06	42761	0.000627	0.78	3190
Children 7-12 yrs:								
0.000001	0.00	>1000000	0.000032	0.04	62482	0.000422	0.53	4735
Females 13+ (preg/not nursing):								
0.000001	0.00	>1000000	0.000031	0.04	64260	0.000463	0.58	4318
Females 13+ (nursing):								
0.000001	0.00	>1000000	0.000038	0.05	52883	0.000495	0.62	4036
Females 13-19 (not preg or nursing):								
0.000001	0.00	>1000000	0.000026	0.03	76859	0.000373	0.47	5358
Females 20+ (not preg or nursing):								
0.000001	0.00	>1000000	0.000035	0.04	56737	0.000381	0.48	5249
Females 13-50 yrs:								
0.000001	0.00	>1000000	0.000033	0.04	59775	0.000389	0.49	5139
Males 13-19 yrs:								
0.000001	0.00	>1000000	0.000030	0.04	67398	0.000423	0.53	4729
Males 20+ yrs:								
0.000001	0.00	>1000000	0.000041	0.05	49224	0.000367	0.46	5445
Seniors 55+:								
0.000001	0.00	>1000000	0.000035	0.04	57298	0.000345	0.43	5803
Custom demographics 1: Workers, 16+ years:								
0.000001	0.00	>1000000	0.000037	0.05	53947	0.000377	0.47	5308

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

U.S. Population — Daily Exposure Analysis /a (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000033	0.000033
Margin of Exposure 2/	803,956	802,567
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.83%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	386,205
40.00	0.000000	0.00	>1,000,000	99.00	0.000038	0.05	53,133
50.00	0.000000	0.00	>1,000,000	99.50	0.000127	0.16	15,802
60.00	0.000000	0.00	>1,000,000	99.75	0.000241	0.30	8,315
70.00	0.000000	0.00	>1,000,000	99.90	0.000416	0.52	4,812
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	387,798
40.00	0.000000	0.00	>1,000,000	99.00	0.000038	0.05	53,323
50.00	0.000000	0.00	>1,000,000	99.50	0.000126	0.16	15,844
60.00	0.000000	0.00	>1,000,000	99.75	0.000240	0.30	8,328
70.00	0.000000	0.00	>1,000,000	99.90	0.000415	0.52	4,817
80.00	0.000000	0.00	>1,000,000				

a/ Analysis based on all two-day participant records in CSFII 1994-98 survey.
2/ Margin of Exposure = NOEL/ Dietary Exposure.

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DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Western region

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000003	0.000003
Standard Deviation	0.000038	0.000038
Margin of Exposure	744,899	742,832
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.72%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000006	0.01	355,472
40.00	0.000000	0.00	>1,000,000	99.00	0.000041	0.05	49,098
50.00	0.000000	0.00	>1,000,000	99.50	0.000133	0.17	15,057
60.00	0.000000	0.00	>1,000,000	99.75	0.000255	0.32	7,831
70.00	0.000000	0.00	>1,000,000	99.90	0.000438	0.55	4,562
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000006	0.01	357,875
40.00	0.000000	0.00	>1,000,000	99.00	0.000040	0.05	49,435
50.00	0.000000	0.00	>1,000,000	99.50	0.000132	0.17	15,109
60.00	0.000000	0.00	>1,000,000	99.75	0.000255	0.32	7,850
70.00	0.000000	0.00	>1,000,000	99.90	0.000438	0.55	4,567
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

All infants

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000009	0.000010
Standard Deviation	0.000127	0.000133
Margin of Exposure	221,088	200,143
Percent of aRfD	0.01	0.01

Percent of Person-Days that are User-Days = 90.53%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000002	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000003	0.00	727,891
30.00	0.000001	0.00	>1,000,000	97.50	0.000013	0.02	156,631
40.00	0.000001	0.00	>1,000,000	99.00	0.000115	0.14	17,335
50.00	0.000001	0.00	>1,000,000	99.50	0.000354	0.44	5,656
60.00	0.000001	0.00	>1,000,000	99.75	0.001259	1.57	1,589
70.00	0.000001	0.00	>1,000,000	99.90	0.002142	2.68	933
80.00	0.000001	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000002	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000002	0.00	826,196
30.00	0.000000	0.00	>1,000,000	97.50	0.000011	0.01	185,333
40.00	0.000001	0.00	>1,000,000	99.00	0.000091	0.11	21,973
50.00	0.000001	0.00	>1,000,000	99.50	0.000299	0.37	6,682
60.00	0.000001	0.00	>1,000,000	99.75	0.001143	1.43	1,749
70.00	0.000001	0.00	>1,000,000	99.90	0.002056	2.57	972
80.00	0.000001	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Nursing infants (<1 yr old)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000003	0.000005
Standard Deviation	0.000063	0.000078
Margin of Exposure	613,719	403,014
Percent of aRfD	0.00	0.01

Percent of Person-Days that are User-Days = 65.67%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000002	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	426,457
40.00	0.000000	0.00	>1,000,000	99.00	0.000038	0.05	53,331
50.00	0.000000	0.00	>1,000,000	99.50	0.000172	0.21	11,631
60.00	0.000000	0.00	>1,000,000	99.75	0.000484	0.60	4,132
70.00	0.000001	0.00	>1,000,000	99.90	0.001396	1.75	1,432
80.00	0.000001	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000002	0.00	853,201
40.00	0.000000	0.00	>1,000,000	99.00	0.000014	0.02	145,410
50.00	0.000000	0.00	>1,000,000	99.50	0.000075	0.09	26,647
60.00	0.000000	0.00	>1,000,000	99.75	0.000239	0.30	8,368
70.00	0.000000	0.00	>1,000,000	99.90	0.000941	1.18	2,125
80.00	0.000001	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Non-nursing infants (<1 yr old) Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000011	0.000011
Standard Deviation	0.000144	0.000144
Margin of Exposure	178,119	177,941
Percent of aRfD	0.01	0.01

Percent of Person-Days that are User-Days = 99.90%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000002	0.00	>1,000,000
20.00	0.000001	0.00	>1,000,000	95.00	0.000003	0.00	605,233
30.00	0.000001	0.00	>1,000,000	97.50	0.000015	0.02	134,020
40.00	0.000001	0.00	>1,000,000	99.00	0.000140	0.17	14,331
50.00	0.000001	0.00	>1,000,000	99.50	0.000417	0.52	4,791
60.00	0.000001	0.00	>1,000,000	99.75	0.001401	1.75	1,427
70.00	0.000001	0.00	>1,000,000	99.90	0.002339	2.92	854
80.00	0.000001	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000002	0.00	>1,000,000
20.00	0.000001	0.00	>1,000,000	95.00	0.000003	0.00	605,951
30.00	0.000001	0.00	>1,000,000	97.50	0.000015	0.02	134,246
40.00	0.000001	0.00	>1,000,000	99.00	0.000139	0.17	14,353
50.00	0.000001	0.00	>1,000,000	99.50	0.000416	0.52	4,803
60.00	0.000001	0.00	>1,000,000	99.75	0.001400	1.75	1,428
70.00	0.000001	0.00	>1,000,000	99.90	0.002338	2.92	855
80.00	0.000001	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Children 1-6 yrs — Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000004	0.000004
Standard Deviation	0.000044	0.000044
Margin of Exposure	571,204	570,793
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.93%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000002	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000007	0.01	288,932
40.00	0.000000	0.00	>1,000,000	99.00	0.000047	0.06	42,705
50.00	0.000000	0.00	>1,000,000	99.50	0.000180	0.22	11,128
60.00	0.000000	0.00	>1,000,000	99.75	0.000354	0.44	5,647
70.00	0.000000	0.00	>1,000,000	99.90	0.000627	0.78	3,189
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000001	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000002	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000007	0.01	289,371
40.00	0.000000	0.00	>1,000,000	99.00	0.000047	0.06	42,761
50.00	0.000000	0.00	>1,000,000	99.50	0.000180	0.22	11,139
60.00	0.000000	0.00	>1,000,000	99.75	0.000354	0.44	5,648
70.00	0.000000	0.00	>1,000,000	99.90	0.000627	0.78	3,190
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Children 7-12 yrs — Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000029	0.000029
Margin of Exposure	828,564	828,174
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.95%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	407,298
40.00	0.000000	0.00	>1,000,000	99.00	0.000032	0.04	62,428
50.00	0.000000	0.00	>1,000,000	99.50	0.000130	0.16	15,356
60.00	0.000000	0.00	>1,000,000	99.75	0.000248	0.31	8,064
70.00	0.000000	0.00	>1,000,000	99.90	0.000422	0.53	4,735
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	407,690
40.00	0.000000	0.00	>1,000,000	99.00	0.000032	0.04	62,482
50.00	0.000000	0.00	>1,000,000	99.50	0.000130	0.16	15,368
60.00	0.000000	0.00	>1,000,000	99.75	0.000248	0.31	8,067
70.00	0.000000	0.00	>1,000,000	99.90	0.000422	0.53	4,735
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13+ (preg/not nursing) Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000027	0.000027
Margin of Exposure	861,633	852,700
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 98.96%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000004	0.00	508,029
40.00	0.000000	0.00	>1,000,000	99.00	0.000033	0.04	60,389
50.00	0.000000	0.00	>1,000,000	99.50	0.000105	0.13	19,062
60.00	0.000000	0.00	>1,000,000	99.75	0.000247	0.31	8,088
70.00	0.000000	0.00	>1,000,000	99.90	0.000464	0.58	4,314
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000004	0.00	532,080
40.00	0.000000	0.00	>1,000,000	99.00	0.000031	0.04	64,260
50.00	0.000000	0.00	>1,000,000	99.50	0.000101	0.13	19,803
60.00	0.000000	0.00	>1,000,000	99.75	0.000247	0.31	8,105
70.00	0.000000	0.00	>1,000,000	99.90	0.000463	0.58	4,318
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13+ (nursing)

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000027	0.000027
Margin of Exposure	850,469	850,469
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	389,389
40.00	0.000000	0.00	>1,000,000	99.00	0.000038	0.05	52,883
50.00	0.000000	0.00	>1,000,000	99.50	0.000116	0.15	17,217
60.00	0.000000	0.00	>1,000,000	99.75	0.000218	0.27	9,159
70.00	0.000000	0.00	>1,000,000	99.90	0.000495	0.62	4,036
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	389,389
40.00	0.000000	0.00	>1,000,000	99.00	0.000038	0.05	52,883
50.00	0.000000	0.00	>1,000,000	99.50	0.000116	0.15	17,217
60.00	0.000000	0.00	>1,000,000	99.75	0.000218	0.27	9,159
70.00	0.000000	0.00	>1,000,000	99.90	0.000495	0.62	4,036
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13-19 (not preg or nursing)Daily Exposure Analysis
(mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000026	0.000026
Margin of Exposure	966,738	966,738
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000003	0.00	574,654
40.00	0.000000	0.00	>1,000,000	99.00	0.000026	0.03	76,859
50.00	0.000000	0.00	>1,000,000	99.50	0.000104	0.13	19,154
60.00	0.000000	0.00	>1,000,000	99.75	0.000228	0.28	8,778
70.00	0.000000	0.00	>1,000,000	99.90	0.000373	0.47	5,358
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000003	0.00	574,654
40.00	0.000000	0.00	>1,000,000	99.00	0.000026	0.03	76,859
50.00	0.000000	0.00	>1,000,000	99.50	0.000104	0.13	19,154
60.00	0.000000	0.00	>1,000,000	99.75	0.000228	0.28	8,778
70.00	0.000000	0.00	>1,000,000	99.90	0.000373	0.47	5,358
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 20+ (not preg or nursing) Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000028	0.000028
Margin of Exposure	885,588	885,475
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.99%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	417,139
40.00	0.000000	0.00	>1,000,000	99.00	0.000035	0.04	56,725
50.00	0.000000	0.00	>1,000,000	99.50	0.000117	0.15	17,077
60.00	0.000000	0.00	>1,000,000	99.75	0.000225	0.28	8,901
70.00	0.000000	0.00	>1,000,000	99.90	0.000381	0.48	5,249
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	417,264
40.00	0.000000	0.00	>1,000,000	99.00	0.000035	0.04	56,737
50.00	0.000000	0.00	>1,000,000	99.50	0.000117	0.15	17,079
60.00	0.000000	0.00	>1,000,000	99.75	0.000225	0.28	8,902
70.00	0.000000	0.00	>1,000,000	99.90	0.000381	0.48	5,249
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13-50 yrs — Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000029	0.000029
Margin of Exposure	876,321	876,103
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	432,016
40.00	0.000000	0.00	>1,000,000	99.00	0.000033	0.04	59,738
50.00	0.000000	0.00	>1,000,000	99.50	0.000117	0.15	17,101
60.00	0.000000	0.00	>1,000,000	99.75	0.000228	0.29	8,762
70.00	0.000000	0.00	>1,000,000	99.90	0.000389	0.49	5,138
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	432,249
40.00	0.000000	0.00	>1,000,000	99.00	0.000033	0.04	59,775
50.00	0.000000	0.00	>1,000,000	99.50	0.000117	0.15	17,106
60.00	0.000000	0.00	>1,000,000	99.75	0.000228	0.29	8,764
70.00	0.000000	0.00	>1,000,000	99.90	0.000389	0.49	5,139
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Males 13-19 yrs — Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000031	0.000031
Margin of Exposure	825,994	825,994
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000004	0.01	448,182
40.00	0.000000	0.00	>1,000,000	99.00	0.000030	0.04	67,398
50.00	0.000000	0.00	>1,000,000	99.50	0.000128	0.16	15,568
60.00	0.000000	0.00	>1,000,000	99.75	0.000264	0.33	7,575
70.00	0.000000	0.00	>1,000,000	99.90	0.000423	0.53	4,729
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000004	0.01	448,182
40.00	0.000000	0.00	>1,000,000	99.00	0.000030	0.04	67,398
50.00	0.000000	0.00	>1,000,000	99.50	0.000128	0.16	15,568
60.00	0.000000	0.00	>1,000,000	99.75	0.000264	0.33	7,575
70.00	0.000000	0.00	>1,000,000	99.90	0.000423	0.53	4,729
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Males 20+ yrs

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000025	0.000025
Margin of Exposure	883,111	882,790
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.96%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	376,481
40.00	0.000000	0.00	>1,000,000	99.00	0.000041	0.05	49,177
50.00	0.000000	0.00	>1,000,000	99.50	0.000123	0.15	16,239
60.00	0.000000	0.00	>1,000,000	99.75	0.000219	0.27	9,122
70.00	0.000000	0.00	>1,000,000	99.90	0.000367	0.46	5,444
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	376,771
40.00	0.000000	0.00	>1,000,000	99.00	0.000041	0.05	49,224
50.00	0.000000	0.00	>1,000,000	99.50	0.000123	0.15	16,250
60.00	0.000000	0.00	>1,000,000	99.75	0.000219	0.27	9,124
70.00	0.000000	0.00	>1,000,000	99.90	0.000367	0.46	5,445
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Seniors 55+ Daily Exposure Analysis
(mg/kg body-weight/day)

	per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000023	0.000023
Margin of Exposure	969,957	969,634
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.97%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	436,295
40.00	0.000000	0.00	>1,000,000	99.00	0.000035	0.04	57,218
50.00	0.000000	0.00	>1,000,000	99.50	0.000112	0.14	17,902
60.00	0.000000	0.00	>1,000,000	99.75	0.000209	0.26	9,556
70.00	0.000000	0.00	>1,000,000	99.90	0.000345	0.43	5,802
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	436,543
40.00	0.000000	0.00	>1,000,000	99.00	0.000035	0.04	57,298
50.00	0.000000	0.00	>1,000,000	99.50	0.000112	0.14	17,909
60.00	0.000000	0.00	>1,000,000	99.75	0.000209	0.26	9,561
70.00	0.000000	0.00	>1,000,000	99.90	0.000345	0.43	5,803
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM Acute analysis for PROPARGITE
Residue file name: H:\MyFiles\DEEM Files\Propargite\propargite water acute.RS7
Analysis Date 10-30-2003 Residue file dated: 10-30-2003/15:13:16/14
Reference dose: aRfD = 0.08 mg/kg bw/day NOEL = 2 mg/kg bw/day

RDL indices and parameters for Monte Carlo Analysis:

Index #	Dist Code	Parameter #1	Param #2	Param #3	Comment
1	6	propwater.rdf			

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	Adj.Factors #2	RDL Ind	Comment
432	O	Water-bottled	0.020000	1.000	1.000	1	
433	O	Water-tap	0.020000	1.000	1.000	1	
434	O	Water-commercial processing	0.020000	1.000	1.000	1	
435	O	Water-non-food based	0.020000	1.000	1.000	1	

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: propargite water acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 10-30-2003/15:36:36 Residue file dated: 10-30-2003/15:13:16/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Custom demographics 1: Workers, 16+ years
All Seasons
All Regions
Sex: M/F-all/
All Races
Age-Low: 16 yrs High: 99 yrs

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000002	0.000002
Standard Deviation	0.000027	0.000027
Margin of Exposure	883,471	883,194
Percent of aRfD	0.00	0.00

Percent of Person-Days that are User-Days = 99.97%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	403,103
40.00	0.000000	0.00	>1,000,000	99.00	0.000037	0.05	53,907
50.00	0.000000	0.00	>1,000,000	99.50	0.000120	0.15	16,722
60.00	0.000000	0.00	>1,000,000	99.75	0.000223	0.28	8,963
70.00	0.000000	0.00	>1,000,000	99.90	0.000377	0.47	5,308
80.00	0.000000	0.00	>1,000,000				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000000	0.00	>1,000,000
20.00	0.000000	0.00	>1,000,000	95.00	0.000001	0.00	>1,000,000
30.00	0.000000	0.00	>1,000,000	97.50	0.000005	0.01	403,433
40.00	0.000000	0.00	>1,000,000	99.00	0.000037	0.05	53,947
50.00	0.000000	0.00	>1,000,000	99.50	0.000120	0.15	16,728
60.00	0.000000	0.00	>1,000,000	99.75	0.000223	0.28	8,964
70.00	0.000000	0.00	>1,000,000	99.90	0.000377	0.47	5,308
80.00	0.000000	0.00	>1,000,000				

California Department of Pesticide Regulation Ver. 7.81
DEEM Acute analysis for PROPARGITE
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Aggregate Acute.RS7
Analysis Date 11-03-2003 Residue file dated: 11-03-2003/14:47:12/14
Reference dose: aRfD = 0.08 mg/kg bw/day NOEL = 2 mg/kg bw/day

RDL indices and parameters for Monte Carlo Analysis:

Index #	Dist Code	Parameter #1	Param #2	Param #3	Comment
1	6	PropGR9600.rdf			
2	6	PropNE0001.rdf			
3	6	PropRA9600.rdf			
4	6	Propwater.rdf			

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	Adj.Factors #2	RDL Ind	Comment
13	O	Grapes	0.720000	1.000	1.000	1	PDP CA
		Full comment: PDP CA grapes RDF					
14	O	Grapes-raisins	0.720000	4.300	1.000	3	PDP CA
		Full comment: PDP CA grapes RDF w/ different PCT					
15	O	Grapes-juice	0.020000	1.000	1.000		PDP 98
		Full comment: PDP 98-99 grape juice CA LOQ					
22	10	Grapefruit-peeled fruit	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
23	10	Grapefruit-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
26	10	Lemons-peeled fruit	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
27	10	Lemons-peel	5.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
28	10	Lemons-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
30	10	Limes-peeled fruit	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
31	10	Limes-peel	5.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
32	10	Limes-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
33	10	Oranges-juice-concentrate	0.020000	3.720	1.000		PDP 97
		Full comment: PDP 97-98 orange juice LOQ					
34	10	Oranges-peeled fruit	0.020000	1.000	1.000		PDP 96
		Full comment: PDP 96, 00-01 orange CA LOQ					
35	10	Oranges-peel	5.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
36	10	Oranges-juice	0.020000	1.000	1.000		PDP 97
		Full comment: PDP 97-98 orange juice LOQ					
38	10	Tangerines	0.020000	1.000	1.000		PDP CA
		Full comment: PDP CA orange used as surrogate					
39	10	Tangerines-juice	0.020000	1.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
40	14	Almonds	0.100000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
48	14	Walnuts	0.100000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
64	12	Nectarines	1.200000	1.000	1.000	2	PDP CA
		Full comment: PDP CA nectarines RDF					
113	O	Tea	10.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					

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125 O    Hops                              15.000000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
195 O    Grapes-leaves                      0.720000   1.000  1.000   1  PDP CA
   Full comment: PDP CA grapes RDF
207 1C   Potatoes/white-whole               0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
208 1C   Potatoes/white-unspecified         0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
209 1C   Potatoes/white-peeled              0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
210 1C   Potatoes/white-dry                 0.020000   6.500  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
211 1C   Potatoes/white-peel only           0.020000   1.000  1.000      PDP 20
   Full comment: PDP 2000-2001 potato CA LOQ
218 1CD  Sweet potatoes (incl yams)         0.020000   1.000  1.000      PDP CA
   Full comment: PDP CA sweet potato data
227 6C   Beans-dry-great northern           0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
228 6C   Beans-dry-kidney                   0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
229 6C   Beans-dry-lima                     0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
230 6C   Beans-dry-navy (pea)               0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
231 6C   Beans-dry-other                    0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
232 6C   Beans-dry-pinto                    0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
237 15   Corn/pop                           0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
238 15   Corn/sweet                         0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn data
244 6C   Mung beans (sprouts)               0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
249 6C   Beans-dry-broadbeans               0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
251 6C   Beans-dry-pigeon beans             0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
256 O    Beans-dry-hyacinth                 0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
258 6C   Beans-dry-blackeye peas/cowpea     0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
259 6C   Beans-dry-garbanzo/chick pea       0.200000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
266 15   Corn grain-endosperm               0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
267 15   Corn grain-bran                    0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
268 15   Corn grain/sugar/hfcs              0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
275 15   Sorghum (including milo)          10.000000   1.000  1.000      U.S. E
   Full comment: U.S. EPA tolerance
289 15   Corn grain-oil                     0.020000   1.000  1.000      PDP sw
   Full comment: PDP sweet corn used as surrogate
290 O    Cottonseed-oil                     0.050000   1.000  1.000      Field
   Full comment: Field trial data
291 O    Cottonseed-meal                    0.050000   1.000  1.000      Field
   Full comment: Field trial data
293 O    Peanuts-oil                        0.013000   1.000  1.000      PDP 20
   Full comment: PDP 2000 peanut butter LOQ
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310	O	Peppermint	2.730000	1.000	1.000	US. EP
		Full comment: US. EPA field trial data				
311	O	Peppermint-oil	2.730000	1.000	1.000	US. EP
		Full comment: US. EPA field trial data				
312	O	Spearmint	4.730000	1.000	1.000	US. EP
		Full comment: US. EPA field trial data				
313	O	Spearmint-oil	4.730000	1.000	1.000	US. EP
		Full comment: US. EPA field trial data				
315	O	Grapes-wine and sherry	0.020000	1.000	1.000	PDP 98
		Full comment: PDP 98-99 grape juice CA LOQ				
318	D	Milk-nonfat solids	0.030000	1.000	1.000	PDP 96
		Full comment: PDP 96-98 whole milk CA LOQ				
319	D	Milk-fat solids	0.030000	1.000	1.000	PDP 96
		Full comment: PDP 96-98 whole milk CA LOQ				
320	D	Milk sugar (lactose)	0.030000	1.000	1.000	PDP 96
		Full comment: PDP 96-98 whole milk CA LOQ				
321	M	Beef-meat byproducts	0.009600	1.000	1.000	PDP 20
		Full comment: PDP 2001 beef liver LOQ				
322	M	Beef-other organ meats	0.009600	1.000	1.000	PDP 20
		Full comment: PDP 2001 beef liver LOQ				
323	M	Beef-dried	0.008600	1.920	1.000	PDP 20
		Full comment: PDP 2001 beef muscle LOQ				
324	M	Beef-fat w/o bones	0.024000	1.000	1.000	PDP 20
		Full comment: PDP 2001 beef adipose LOQ				
325	M	Beef-kidney	0.009600	1.000	1.000	PDP 20
		Full comment: PDP 2001 beef liver LOQ				
326	M	Beef-liver	0.009600	1.000	1.000	PDP 20
		Full comment: PDP 2001 beef liver LOQ				
327	M	Beef-lean (fat/free) w/o bones	0.008600	1.000	1.000	PDP 20
		Full comment: PDP 2001 beef muscle LOQ				
328	M	Goat-meat byproducts	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
329	M	Goat-other organ meats	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
330	M	Goat-fat w/o bone	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
331	M	Goat-kidney	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
332	M	Goat-liver	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
333	M	Goat-lean (fat/free) w/o bone	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
334	M	Horsemeat	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
336	M	Sheep-meat byproducts	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
337	M	Sheep-other organ meats	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
338	M	Sheep-fat w/o bone	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
339	M	Sheep-kidney	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
340	M	Sheep-liver	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
341	M	Sheep-lean (fat free) w/o bone	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
342	M	Pork-meat byproducts	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				
343	M	Pork-other organ meats	0.100000	1.000	1.000	U.S. E
		Full comment: U.S. EPA tolerance				

344 M Pork-fat w/o bone 0.100000 1.000 1.000 U.S. E
  Full comment: U.S. EPA tolerance
345 M Pork-kidney 0.100000 1.000 1.000 U.S. E
  Full comment: U.S. EPA tolerance
346 M Pork-liver 0.100000 1.000 1.000 U.S. E
  Full comment: U.S. EPA tolerance
347 M Pork-lean (fat free) w/o bone 0.100000 1.000 1.000 U.S. E
  Full comment: U.S. EPA tolerance
355 P Turkey-byproducts 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
356 P Turkey-giblets (liver) 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
357 P Turkey--fat w/o bones 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
358 P Turkey- lean/fat free w/o bones 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
360 P Poultry-other-lean (fat free) w/ 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
361 P Poultry-other-giblets(liver) 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
362 P Poultry-other-fat w/o bones 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
363 P Eggs-whole 0.100000 1.000 1.000 U.S. E
  Full comment: U.S. EPA tolerance
364 P Eggs-white only 0.100000 1.000 1.000 U.S. E
  Full comment: U.S. EPA tolerance
365 P Eggs-yolk only 0.100000 1.000 1.000 U.S. E
  Full comment: U.S. EPA tolerance
366 P Chicken-byproducts 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
367 P Chicken-giblets(liver) 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
368 P Chicken-fat w/o bones 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
369 P Chicken-lean/fat free w/o bones 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
385 P Chicken-giblets (excl. liver) 0.033000 1.000 1.000 PDP 20
  Full comment: PDP 2000-2001 poultry LOQ
388 15 Corn grain/sugar-molasses 0.020000 1.000 1.000 PDP sw
  Full comment: PDP sweet corn used as surrogate
392 O Grapes-juice-concentrate 0.020000 3.000 1.000 PDP 98
  Full comment: PDP 98-99 grape juice CA LOQ
398 D Milk-based water 0.030000 1.000 1.000 PDP 96
  Full comment: PDP 96-98 whole milk CA LOQ
403 O Peanuts-butter 0.013000 1.000 1.000 PDP 20
  Full comment: PDP 2000 peanut butter LOQ
418 2 Sweet potatos-leaves 0.020000 1.000 1.000 PDP CA
  Full comment: PDP CA sweet potato data
420 10 Tangerines-juice-concentrate 0.020000 3.200 1.000 PDP or
  Full comment: PDP orange juice used as surrogate
424 M Veal-fat w/o bones 0.024000 1.000 1.000 PDP 20
  Full comment: PDP 2001 beef adipose LOQ
425 M Veal-lean (fat free) w/o bones 0.008600 1.000 1.000 PDP 20
  Full comment: PDP 2001 beef muscle LOQ
426 M Veal-kidney 0.009600 1.000 1.000 PDP 20
  Full comment: PDP 2001 beef liver LOQ
427 M Veal-liver 0.009600 1.000 1.000 PDP 20
  Full comment: PDP 2001 beef liver LOQ
428 M Veal-other organ meats 0.009600 1.000 1.000 PDP 20
  Full comment: PDP 2001 beef liver LOQ

429	M	Veal-dried	0.008600	1.920	1.000		PDP 20
		Full comment: PDP 2001 beef muscle LOQ					
430	M	Veal-meat byproducts	0.009600	1.000	1.000		PDP 20
		Full comment: PDP 2001 beef liver LOQ					
431	14	Walnut oil	0.100000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
432	O	Water-bottled	0.020000	1.000	1.000	4	DPR su
		Full comment: DPR surface water RDF					
433	O	Water-tap	0.020000	1.000	1.000	4	DPR su
		Full comment: DPR surface water RDF					
434	O	Water-commercial processing	0.020000	1.000	1.000	4	DPR su
		Full comment: DPR surface water RDF					
435	O	Water-non-food based	0.020000	1.000	1.000	4	DPR su
		Full comment: DPR surface water RDF					
441	10	Grapefruit-juice-concentrate	0.020000	3.930	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
442	10	Lemons-juice-concentrate	0.020000	5.700	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
443	10	Limes-juice-concentrate	0.020000	3.000	1.000		PDP or
		Full comment: PDP orange juice used as surrogate					
448	10	Grapefruit peel	5.000000	1.000	1.000		U.S. E
		Full comment: U.S. EPA tolerance					
449	P	Turkey-other organ meats	0.033000	1.000	1.000		PDP 20
		Full comment: PDP 2000-2001 poultry LOQ					
940	O	Peanuts-hulled	0.013000	1.000	1.000		PDP 20
		Full comment: PDP 2000 peanut butter LOQ					

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Run Comment: ""

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. Population:								
0.001467	1.83	1363	0.002533	3.17	789	0.004357	5.45	459
Western region:								
0.001535	1.92	1303	0.002581	3.23	774	0.004289	5.36	466
All infants:								
0.002112	2.64	947	0.004669	5.84	428	0.006024	7.53	332
Nursing infants (<1 yr old):								
0.000747	0.93	2677	0.001577	1.97	1267	0.004065	5.08	491
Non-nursing infants (<1 yr old):								
0.002522	3.15	793	0.004875	6.09	410	0.006221	7.78	321
Children 1-6 yrs:								
0.002922	3.65	684	0.004205	5.26	475	0.006801	8.50	294
Children 7-12 yrs:								
0.001495	1.87	1337	0.002152	2.69	929	0.003237	4.05	617
Females 13+ (preg/not nursing):								
0.001000	1.25	2000	0.001341	1.68	1491	0.001698	2.12	1177
Females 13+ (nursing):								
0.001009	1.26	1981	0.001211	1.51	1651	0.001804	2.26	1108
Females 13-19 (not preg or nursing):								
0.000938	1.17	2131	0.001307	1.63	1530	0.001818	2.27	1100
Females 20+ (not preg or nursing):								
0.000854	1.07	2340	0.001240	1.55	1612	0.002094	2.62	954
Females 13-50 yrs:								
0.000897	1.12	2229	0.001328	1.66	1506	0.002095	2.62	954
Males 13-19 yrs:								
0.001248	1.56	1602	0.001862	2.33	1074	0.003156	3.94	633
Males 20+ yrs:								
0.001044	1.31	1915	0.001720	2.15	1162	0.003017	3.77	662
Seniors 55+:								
0.000786	0.98	2544	0.001174	1.47	1703	0.002143	2.68	933
Custom demographics 1: Workers, 16+ yrs:								
0.000941	1.18	2125	0.001525	1.91	1311	0.002728	3.41	733

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Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

U.S. Population — Daily Exposure Analysis /a (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000524	0.000525
Standard Deviation	0.000505	0.000505
Margin of Exposure 2/	3,817	3,812
Percent of aRfD	0.65	0.66

Percent of Person-Days that are User-Days = 99.85%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000125	0.16	16,020	90.00	0.001076	1.35	1,858
20.00	0.000191	0.24	10,496	95.00	0.001468	1.83	1,362
30.00	0.000251	0.31	7,969	97.50	0.001903	2.38	1,051
40.00	0.000313	0.39	6,384	99.00	0.002534	3.17	789
50.00	0.000384	0.48	5,210	99.50	0.003028	3.78	660
60.00	0.000463	0.58	4,315	99.75	0.003527	4.41	566
70.00	0.000571	0.71	3,505	99.90	0.004358	5.45	458
80.00	0.000741	0.93	2,697				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000124	0.15	16,156	90.00	0.001075	1.34	1,859
20.00	0.000190	0.24	10,538	95.00	0.001467	1.83	1,363
30.00	0.000250	0.31	7,990	97.50	0.001902	2.38	1,051
40.00	0.000313	0.39	6,395	99.00	0.002533	3.17	789
50.00	0.000383	0.48	5,217	99.50	0.003026	3.78	660
60.00	0.000463	0.58	4,319	99.75	0.003526	4.41	567
70.00	0.000570	0.71	3,509	99.90	0.004357	5.45	459
80.00	0.000741	0.93	2,699				

a/ Analysis based on all two-day participant records in CSFII 1994-98 survey.
2/ Margin of Exposure = NOEL/ Dietary Exposure.

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NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Western region

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000547	0.000548
Standard Deviation	0.000523	0.000523
Margin of Exposure	3,658	3,649
Percent of aRfD	0.68	0.68

Percent of Person-Days that are User-Days = 99.76%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000124	0.16	16,123	90.00	0.001132	1.42	1,766
20.00	0.000197	0.25	10,177	95.00	0.001536	1.92	1,301
30.00	0.000262	0.33	7,630	97.50	0.001991	2.49	1,004
40.00	0.000328	0.41	6,104	99.00	0.002583	3.23	774
50.00	0.000399	0.50	5,010	99.50	0.003109	3.89	643
60.00	0.000483	0.60	4,144	99.75	0.003544	4.43	564
70.00	0.000597	0.75	3,350	99.90	0.004290	5.36	466
80.00	0.000786	0.98	2,544				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000122	0.15	16,342	90.00	0.001131	1.41	1,769
20.00	0.000195	0.24	10,248	95.00	0.001535	1.92	1,303
30.00	0.000261	0.33	7,662	97.50	0.001990	2.49	1,005
40.00	0.000327	0.41	6,120	99.00	0.002581	3.23	774
50.00	0.000398	0.50	5,022	99.50	0.003107	3.88	643
60.00	0.000481	0.60	4,155	99.75	0.003541	4.43	564
70.00	0.000596	0.75	3,355	99.90	0.004289	5.36	466
80.00	0.000785	0.98	2,549				

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NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

All infants

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000537	0.000592
Standard Deviation	0.000804	0.000825
Margin of Exposure	3,725	3,375
Percent of aRfD	0.67	0.74

Percent of Person-Days that are User-Days = 90.61%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000079	0.10	25,342	90.00	0.001278	1.60	1,565
20.00	0.000127	0.16	15,704	95.00	0.002248	2.81	889
30.00	0.000200	0.25	9,990	97.50	0.003198	4.00	625
40.00	0.000283	0.35	7,069	99.00	0.004768	5.96	419
50.00	0.000359	0.45	5,573	99.50	0.005464	6.83	366
60.00	0.000437	0.55	4,580	99.75	0.005739	7.17	348
70.00	0.000542	0.68	3,688	99.90	0.006222	7.78	321
80.00	0.000732	0.92	2,730				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000001	0.00	>1,000,000	90.00	0.001158	1.45	1,727
20.00	0.000089	0.11	22,544	95.00	0.002112	2.64	947
30.00	0.000141	0.18	14,209	97.50	0.003017	3.77	662
40.00	0.000237	0.30	8,446	99.00	0.004669	5.84	428
50.00	0.000321	0.40	6,239	99.50	0.005340	6.68	374
60.00	0.000403	0.50	4,965	99.75	0.005710	7.14	350
70.00	0.000507	0.63	3,941	99.90	0.006024	7.53	332
80.00	0.000689	0.86	2,902				

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NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Nursing infants (<1 yr old)

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000175	0.000267
Standard Deviation	0.000369	0.000428
Margin of Exposure	11,412	7,500
Percent of aRfD	0.22	0.33

Percent of Person-Days that are User-Days = 65.72%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	0.00	>1,000,000	90.00	0.000661	0.83	3,024
20.00	0.000011	0.01	188,601	95.00	0.000943	1.18	2,120
30.00	0.000053	0.07	37,863	97.50	0.001293	1.62	1,547
40.00	0.000087	0.11	23,006	99.00	0.002153	2.69	928
50.00	0.000137	0.17	14,649	99.50	0.002764	3.45	723
60.00	0.000209	0.26	9,560	99.75	0.003282	4.10	609
70.00	0.000284	0.35	7,045	99.90	0.004079	5.10	490
80.00	0.000384	0.48	5,210				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000481	0.60	4,160
20.00	0.000000	0.00	>1,000,000	95.00	0.000747	0.93	2,677
30.00	0.000000	0.00	>1,000,000	97.50	0.001127	1.41	1,773
40.00	0.000002	0.00	>1,000,000	99.00	0.001577	1.97	1,267
50.00	0.000025	0.03	79,860	99.50	0.002209	2.76	905
60.00	0.000084	0.11	23,795	99.75	0.003257	4.07	614
70.00	0.000157	0.20	12,712	99.90	0.004065	5.08	491
80.00	0.000277	0.35	7,215				

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DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Aggregate Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:32:54 Residue file dated: 11-03-2003/14:47:12/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Non-nursing infants (<1 yr old) Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000673	0.000673
Standard Deviation	0.000878	0.000878
Margin of Exposure	2,970	2,970
Percent of aRfD	0.84	0.84

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000113	0.14	17,744	90.00	0.001521	1.90	1,315
20.00	0.000173	0.22	11,534	95.00	0.002522	3.15	793
30.00	0.000266	0.33	7,529	97.50	0.003344	4.18	598
40.00	0.000340	0.43	5,876	99.00	0.004875	6.09	410
50.00	0.000407	0.51	4,917	99.50	0.005479	6.85	364
60.00	0.000484	0.60	4,134	99.75	0.005771	7.21	346
70.00	0.000599	0.75	3,338	99.90	0.006221	7.78	321
80.00	0.000807	1.01	2,479				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000113	0.14	17,744	90.00	0.001521	1.90	1,315
20.00	0.000173	0.22	11,534	95.00	0.002522	3.15	793
30.00	0.000266	0.33	7,529	97.50	0.003344	4.18	598
40.00	0.000340	0.43	5,876	99.00	0.004875	6.09	410
50.00	0.000407	0.51	4,917	99.50	0.005479	6.85	364
60.00	0.000484	0.60	4,134	99.75	0.005771	7.21	346
70.00	0.000599	0.75	3,338	99.90	0.006221	7.78	321
80.00	0.000807	1.01	2,479				

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Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Children 1-6 yrs

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.001394	0.001394
Standard Deviation	0.000845	0.000845
Margin of Exposure	1,434	1,434
Percent of aRfD	1.74	1.74

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000530	0.66	3,770	90.00	0.002416	3.02	827
20.00	0.000738	0.92	2,710	95.00	0.002922	3.65	684
30.00	0.000912	1.14	2,193	97.50	0.003432	4.29	582
40.00	0.001069	1.34	1,871	99.00	0.004205	5.26	475
50.00	0.001235	1.54	1,619	99.50	0.004879	6.10	409
60.00	0.001422	1.78	1,406	99.75	0.005594	6.99	357
70.00	0.001630	2.04	1,226	99.90	0.006801	8.50	294
80.00	0.001927	2.41	1,037				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000530	0.66	3,770	90.00	0.002416	3.02	827
20.00	0.000738	0.92	2,710	95.00	0.002922	3.65	684
30.00	0.000912	1.14	2,193	97.50	0.003432	4.29	582
40.00	0.001069	1.34	1,871	99.00	0.004205	5.26	475
50.00	0.001235	1.54	1,619	99.50	0.004879	6.10	409
60.00	0.001422	1.78	1,406	99.75	0.005594	6.99	357
70.00	0.001630	2.04	1,226	99.90	0.006801	8.50	294
80.00	0.001927	2.41	1,037				

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NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Children 7-12 yrs

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000741	0.000741
Standard Deviation	0.000423	0.000423
Margin of Exposure	2,698	2,698
Percent of aRfD	0.93	0.93

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000282	0.35	7,085	90.00	0.001264	1.58	1,581
20.00	0.000390	0.49	5,127	95.00	0.001495	1.87	1,337
30.00	0.000491	0.61	4,069	97.50	0.001742	2.18	1,147
40.00	0.000583	0.73	3,429	99.00	0.002152	2.69	929
50.00	0.000675	0.84	2,963	99.50	0.002349	2.94	851
60.00	0.000778	0.97	2,571	99.75	0.002638	3.30	758
70.00	0.000883	1.10	2,265	99.90	0.003237	4.05	617
80.00	0.001029	1.29	1,943				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000282	0.35	7,085	90.00	0.001264	1.58	1,581
20.00	0.000390	0.49	5,127	95.00	0.001495	1.87	1,337
30.00	0.000491	0.61	4,069	97.50	0.001742	2.18	1,147
40.00	0.000583	0.73	3,429	99.00	0.002152	2.69	929
50.00	0.000675	0.84	2,963	99.50	0.002349	2.94	851
60.00	0.000778	0.97	2,571	99.75	0.002638	3.30	758
70.00	0.000883	1.10	2,265	99.90	0.003237	4.05	617
80.00	0.001029	1.29	1,943				

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Residue file: Propargite Aggregate Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:32:54 Residue file dated: 11-03-2003/14:47:12/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13+ (preg/not nursing)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000449	0.000449
Standard Deviation	0.000306	0.000306
Margin of Exposure	4,455	4,455
Percent of aRfD	0.56	0.56

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000105	0.13	19,125	90.00	0.000852	1.06	2,348
20.00	0.000203	0.25	9,875	95.00	0.001000	1.25	2,000
30.00	0.000248	0.31	8,062	97.50	0.001251	1.56	1,598
40.00	0.000306	0.38	6,525	99.00	0.001341	1.68	1,491
50.00	0.000374	0.47	5,350	99.50	0.001628	2.04	1,228
60.00	0.000471	0.59	4,244	99.75	0.001646	2.06	1,214
70.00	0.000582	0.73	3,438	99.90	0.001698	2.12	1,177
80.00	0.000660	0.82	3,030				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000105	0.13	19,125	90.00	0.000852	1.06	2,348
20.00	0.000203	0.25	9,875	95.00	0.001000	1.25	2,000
30.00	0.000248	0.31	8,062	97.50	0.001251	1.56	1,598
40.00	0.000306	0.38	6,525	99.00	0.001341	1.68	1,491
50.00	0.000374	0.47	5,350	99.50	0.001628	2.04	1,228
60.00	0.000471	0.59	4,244	99.75	0.001646	2.06	1,214
70.00	0.000582	0.73	3,438	99.90	0.001698	2.12	1,177
80.00	0.000660	0.82	3,030				

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Residue file: Propargite Aggregate Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:32:54 Residue file dated: 11-03-2003/14:47:12/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13+ (nursing)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000478	0.000478
Standard Deviation	0.000269	0.000269
Margin of Exposure	4,183	4,183
Percent of aRfD	0.60	0.60

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000196	0.25	10,199	90.00	0.000841	1.05	2,377
20.00	0.000276	0.34	7,252	95.00	0.001009	1.26	1,981
30.00	0.000322	0.40	6,207	97.50	0.001201	1.50	1,665
40.00	0.000364	0.45	5,495	99.00	0.001211	1.51	1,651
50.00	0.000419	0.52	4,772	99.50	0.001360	1.70	1,470
60.00	0.000477	0.60	4,197	99.75	0.001375	1.72	1,454
70.00	0.000554	0.69	3,608	99.90	0.001804	2.26	1,108
80.00	0.000692	0.87	2,889				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000196	0.25	10,199	90.00	0.000841	1.05	2,377
20.00	0.000276	0.34	7,252	95.00	0.001009	1.26	1,981
30.00	0.000322	0.40	6,207	97.50	0.001201	1.50	1,665
40.00	0.000364	0.45	5,495	99.00	0.001211	1.51	1,651
50.00	0.000419	0.52	4,772	99.50	0.001360	1.70	1,470
60.00	0.000477	0.60	4,197	99.75	0.001375	1.72	1,454
70.00	0.000554	0.69	3,608	99.90	0.001804	2.26	1,108
80.00	0.000692	0.87	2,889				

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Residue file: Propargite Aggregate Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:32:54 Residue file dated: 11-03-2003/14:47:12/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13-19 (not preg or nursing) Daily Exposure Analysis
(mg/kg body-weight/day)

	per Capita	per User
Mean	0.000393	0.000393
Standard Deviation	0.000279	0.000279
Margin of Exposure	5,084	5,084
Percent of aRfD	0.49	0.49

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000098	0.12	20,436	90.00	0.000755	0.94	2,650
20.00	0.000160	0.20	12,488	95.00	0.000938	1.17	2,131
30.00	0.000217	0.27	9,207	97.50	0.001130	1.41	1,769
40.00	0.000272	0.34	7,341	99.00	0.001307	1.63	1,530
50.00	0.000332	0.42	6,021	99.50	0.001422	1.78	1,406
60.00	0.000402	0.50	4,969	99.75	0.001582	1.98	1,264
70.00	0.000481	0.60	4,155	99.90	0.001818	2.27	1,100
80.00	0.000582	0.73	3,438				

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000098	0.12	20,436	90.00	0.000755	0.94	2,650
20.00	0.000160	0.20	12,488	95.00	0.000938	1.17	2,131
30.00	0.000217	0.27	9,207	97.50	0.001130	1.41	1,769
40.00	0.000272	0.34	7,341	99.00	0.001307	1.63	1,530
50.00	0.000332	0.42	6,021	99.50	0.001422	1.78	1,406
60.00	0.000402	0.50	4,969	99.75	0.001582	1.98	1,264
70.00	0.000481	0.60	4,155	99.90	0.001818	2.27	1,100
80.00	0.000582	0.73	3,438				

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Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 20+ (not preg or nursing) Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000357	0.000357
Standard Deviation	0.000263	0.000263
Margin of Exposure	5,608	5,608
Percent of aRfD	0.45	0.45

Percent of Person-Days that are User-Days = 99.99%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000103	0.13	19,388	90.00	0.000673	0.84	2,970
20.00	0.000152	0.19	13,162	95.00	0.000854	1.07	2,340
30.00	0.000199	0.25	10,069	97.50	0.001003	1.25	1,993
40.00	0.000246	0.31	8,123	99.00	0.001240	1.55	1,612
50.00	0.000299	0.37	6,681	99.50	0.001510	1.89	1,324
60.00	0.000359	0.45	5,576	99.75	0.001666	2.08	1,200
70.00	0.000424	0.53	4,722	99.90	0.002094	2.62	954
80.00	0.000513	0.64	3,898				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000103	0.13	19,392	90.00	0.000673	0.84	2,971
20.00	0.000152	0.19	13,165	95.00	0.000854	1.07	2,340
30.00	0.000199	0.25	10,070	97.50	0.001003	1.25	1,993
40.00	0.000246	0.31	8,124	99.00	0.001240	1.55	1,612
50.00	0.000299	0.37	6,682	99.50	0.001510	1.89	1,324
60.00	0.000359	0.45	5,577	99.75	0.001666	2.08	1,200
70.00	0.000424	0.53	4,722	99.90	0.002094	2.62	954
80.00	0.000513	0.64	3,898				

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Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Females 13-50 yrs

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000372	0.000372
Standard Deviation	0.000277	0.000277
Margin of Exposure	5,378	5,378
Percent of aRfD	0.46	0.46

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000099	0.12	20,115	90.00	0.000723	0.90	2,765
20.00	0.000150	0.19	13,354	95.00	0.000897	1.12	2,229
30.00	0.000201	0.25	9,972	97.50	0.001068	1.33	1,873
40.00	0.000254	0.32	7,877	99.00	0.001328	1.66	1,506
50.00	0.000310	0.39	6,450	99.50	0.001524	1.90	1,312
60.00	0.000372	0.47	5,374	99.75	0.001716	2.14	1,165
70.00	0.000444	0.56	4,501	99.90	0.002095	2.62	954
80.00	0.000551	0.69	3,629				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000099	0.12	20,115	90.00	0.000723	0.90	2,765
20.00	0.000150	0.19	13,354	95.00	0.000897	1.12	2,229
30.00	0.000201	0.25	9,972	97.50	0.001068	1.33	1,873
40.00	0.000254	0.32	7,877	99.00	0.001328	1.66	1,506
50.00	0.000310	0.39	6,450	99.50	0.001524	1.90	1,312
60.00	0.000372	0.47	5,374	99.75	0.001716	2.14	1,165
70.00	0.000444	0.56	4,501	99.90	0.002095	2.62	954
80.00	0.000551	0.69	3,629				

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Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Males 13-19 yrs

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000516	0.000516
Standard Deviation	0.000380	0.000380
Margin of Exposure	3,878	3,878
Percent of aRfD	0.64	0.64

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000150	0.19	13,349	90.00	0.000944	1.18	2,117
20.00	0.000231	0.29	8,673	95.00	0.001248	1.56	1,602
30.00	0.000296	0.37	6,751	97.50	0.001476	1.84	1,355
40.00	0.000363	0.45	5,515	99.00	0.001862	2.33	1,074
50.00	0.000429	0.54	4,665	99.50	0.002303	2.88	868
60.00	0.000511	0.64	3,915	99.75	0.002885	3.61	693
70.00	0.000602	0.75	3,320	99.90	0.003156	3.94	633
80.00	0.000750	0.94	2,666				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000150	0.19	13,349	90.00	0.000944	1.18	2,117
20.00	0.000231	0.29	8,673	95.00	0.001248	1.56	1,602
30.00	0.000296	0.37	6,751	97.50	0.001476	1.84	1,355
40.00	0.000363	0.45	5,515	99.00	0.001862	2.33	1,074
50.00	0.000429	0.54	4,665	99.50	0.002303	2.88	868
60.00	0.000511	0.64	3,915	99.75	0.002885	3.61	693
70.00	0.000602	0.75	3,320	99.90	0.003156	3.94	633
80.00	0.000750	0.94	2,666				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Aggregate Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:32:54 Residue file dated: 11-03-2003/14:47:12/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Males 20+ yrs

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000429	0.000429
Standard Deviation	0.000340	0.000340
Margin of Exposure	4,662	4,660
Percent of aRfD	0.54	0.54

Percent of Person-Days that are User-Days = 99.97%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000127	0.16	15,765	90.00	0.000802	1.00	2,494
20.00	0.000188	0.24	10,627	95.00	0.001044	1.31	1,914
30.00	0.000242	0.30	8,266	97.50	0.001297	1.62	1,541
40.00	0.000291	0.36	6,876	99.00	0.001720	2.15	1,162
50.00	0.000350	0.44	5,711	99.50	0.002179	2.72	917
60.00	0.000415	0.52	4,819	99.75	0.002574	3.22	777
70.00	0.000491	0.61	4,069	99.90	0.003018	3.77	662
80.00	0.000598	0.75	3,343				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000127	0.16	15,790	90.00	0.000802	1.00	2,494
20.00	0.000188	0.24	10,635	95.00	0.001044	1.31	1,915
30.00	0.000242	0.30	8,271	97.50	0.001297	1.62	1,541
40.00	0.000291	0.36	6,879	99.00	0.001720	2.15	1,162
50.00	0.000350	0.44	5,713	99.50	0.002178	2.72	918
60.00	0.000415	0.52	4,820	99.75	0.002573	3.22	777
70.00	0.000491	0.61	4,070	99.90	0.003017	3.77	662
80.00	0.000598	0.75	3,344				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Aggregate Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:32:54 Residue file dated: 11-03-2003/14:47:12/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Seniors 55+ Daily Exposure Analysis
(mg/kg body-weight/day)

	per Capita	per User
Mean	0.000357	0.000357
Standard Deviation	0.000243	0.000243
Margin of Exposure	5,599	5,598
Percent of aRfD	0.45	0.45

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000118	0.15	16,886	90.00	0.000637	0.80	3,138
20.00	0.000173	0.22	11,546	95.00	0.000786	0.98	2,544
30.00	0.000218	0.27	9,160	97.50	0.000954	1.19	2,097
40.00	0.000262	0.33	7,633	99.00	0.001174	1.47	1,703
50.00	0.000308	0.38	6,501	99.50	0.001421	1.78	1,407
60.00	0.000359	0.45	5,565	99.75	0.001603	2.00	1,247
70.00	0.000425	0.53	4,706	99.90	0.002143	2.68	933
80.00	0.000501	0.63	3,991				

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000118	0.15	16,904	90.00	0.000637	0.80	3,138
20.00	0.000173	0.22	11,552	95.00	0.000786	0.98	2,544
30.00	0.000218	0.27	9,163	97.50	0.000954	1.19	2,097
40.00	0.000262	0.33	7,635	99.00	0.001174	1.47	1,703
50.00	0.000308	0.38	6,502	99.50	0.001421	1.78	1,407
60.00	0.000359	0.45	5,566	99.75	0.001603	2.00	1,247
70.00	0.000425	0.53	4,707	99.90	0.002143	2.68	933
80.00	0.000501	0.63	3,992				

California Department of Pesticide Regulation Ver. 7.81
DEEM ACUTE Analysis for PROPARGITE (1994-98 data)
Residue file: Propargite Aggregate Acute.RS7 Adjustment factor #2 NOT used.
Analysis Date: 11-03-2003/15:32:54 Residue file dated: 11-03-2003/14:47:12/14
NOEL (Acute) = 2.000000 mg/kg body-wt/day
Acute Reference Dose (aRfD) = 0.080000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
MC iterations = 100 MC list in residue file MC seed = 1
Run Comment: ""

Custom demographics 1: Workers, 16+ yrs
All Seasons
All Regions
Sex: M/F-all/
All Races
Age-Low: 16 yrs High: 99 yrs

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000395	0.000395
Standard Deviation	0.000307	0.000307
Margin of Exposure	5,063	5,062
Percent of aRfD	0.49	0.49

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000112	0.14	17,823	90.00	0.000748	0.94	2,673
20.00	0.000169	0.21	11,851	95.00	0.000941	1.18	2,125
30.00	0.000221	0.28	9,065	97.50	0.001166	1.46	1,715
40.00	0.000270	0.34	7,416	99.00	0.001525	1.91	1,311
50.00	0.000325	0.41	6,157	99.50	0.001814	2.27	1,102
60.00	0.000389	0.49	5,136	99.75	0.002234	2.79	895
70.00	0.000461	0.58	4,341	99.90	0.002728	3.41	733
80.00	0.000561	0.70	3,568				

Estimated percentile of per-capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000112	0.14	17,837	90.00	0.000748	0.93	2,673
20.00	0.000169	0.21	11,856	95.00	0.000941	1.18	2,125
30.00	0.000221	0.28	9,067	97.50	0.001166	1.46	1,715
40.00	0.000270	0.34	7,418	99.00	0.001525	1.91	1,311
50.00	0.000325	0.41	6,158	99.50	0.001814	2.27	1,102
60.00	0.000389	0.49	5,137	99.75	0.002234	2.79	895
70.00	0.000461	0.58	4,342	99.90	0.002728	3.41	733
80.00	0.000560	0.70	3,568				

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE 1994-98 data
Residue file: H:\MyFiles\DEEM Files\Propargite\Propargite Chronic.RS7
Adjust. #2 used
Analysis Date 11-06-2003 Residue file dated: 11-06-2003/15:11:58/14
Reference dose (RfD) = 0.04 (NOEL) = 3.8 mg/kg bw/day

Food Code	Crop Grp	Food Name	RESIDUE (ppm)	Adj.Factors #1	#2	Comment
13	O	Grapes	0.005100	1.000	1.000	PDP CA
		Full comment: PDP CA grapes				
14	O	Grapes-raisins	0.008000	4.300	1.000	PDP CA
		Full comment: PDP CA grapes w/ different PCT				
15	O	Grapes-juice	0.010000	1.000	1.000	PDP 98
		Full comment: PDP 98-99 CA grape juice 1/2 LOQ				
22	10	Grapefruit-peeled fruit	0.010000	1.000	0.020	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
23	10	Grapefruit-juice	0.010000	1.000	0.020	PDP or
		Full comment: PDP orange juice 1/2 LOQ as surrogate				
26	10	Lemons-peeled fruit	0.010000	1.000	0.010	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
27	10	Lemons-peel	2.500000	1.000	0.010	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
28	10	Lemons-juice	0.010000	1.000	1.000	PDP CA
		Full comment: PDP CA orange juice 1/2 LOQ as surrogate				
30	10	Limes-peeled fruit	0.010000	1.000	0.010	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
31	10	Limes-peel	2.500000	1.000	0.010	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
32	10	Limes-juice	0.010000	1.000	1.000	PDP CA
		Full comment: PDP CA orange juice 1/2 LOQ as surrogate				
33	10	Oranges-juice-concentrate	0.010000	3.720	1.000	PDP 97
		Full comment: PDP 97-98 CA orange juice 1/2 LOQ				
34	10	Oranges-peeled fruit	0.010000	1.000	0.020	PDP 96
		Full comment: PDP 96, 00-01 CA orange 1/2 LOQ				
35	10	Oranges-peel	2.500000	1.000	0.020	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
36	10	Oranges-juice	0.010000	1.000	1.000	PDP 97
		Full comment: PDP 97-98 CA orange juice 1/2 LOQ				
38	10	Tangerines	0.010000	1.000	0.020	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
39	10	Tangerines-juice	0.010000	1.000	1.000	PDP CA
		Full comment: PDP CA orange juice 1/2 LOQ as surrogate				
40	14	Almonds	0.050000	1.000	0.350	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
48	14	Walnuts	0.050000	1.000	0.250	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
64	12	Nectarines	0.128000	1.000	1.000	PDP CA
		Full comment: PDP CA nectarines				
113	O	Tea	5.000000	1.000	0.060	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
125	O	Hops	7.500000	1.000	0.050	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
195	O	Grapes-leaves	0.005100	1.000	1.000	PDP CA
		Full comment: PDP CA grapes				
207	1C	Potatoes/white-whole	0.010000	1.000	0.020	PDP 20
		Full comment: PDP 2000-2001 potato CA 1/2 LOQ				
208	1C	Potatoes/white-unspecified	0.010000	1.000	0.020	PDP 20

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 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
209 1C   Potatoes/white-peeled              0.010000       1.000  0.020 PDP 20
 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
210 1C   Potatoes/white-dry                 0.010000       6.500  0.020 PDP 20
 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
211 1C   Potatoes/white-peel only           0.010000       1.000  0.020 PDP 20
 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
218 1CD  Sweet potatoes (incl yams)         0.010000       1.000  0.020 PDP CA
 Full comment: PDP CA sweet potato 1/2 LOQ
227 6C   Beans-dry-great northern           0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
228 6C   Beans-dry-kidney                   0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
229 6C   Beans-dry-lima                     0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
230 6C   Beans-dry-navy (pea)               0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
231 6C   Beans-dry-other                    0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
232 6C   Beans-dry-pinto                    0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
237 15   Corn/pop                           0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
238 15   Corn/sweet                         0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ
244 6C   Mung beans (sprouts)               0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
249 6C   Beans-dry-broadbeans               0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
251 6C   Beans-dry-pigeon beans             0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
256      Beans-dry-hyacinth                 0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
258 6C   Beans-dry-blackeye peas/cowpea     0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
259 6C   Beans-dry-garbanzo/chick pea       0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
266 15   Corn grain-endosperm               0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
267 15   Corn grain-bran                    0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
268 15   Corn grain/sugar/hfcs              0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
275 15   Sorghum (including milo)           5.000000       1.000  0.010 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
289 15   Corn grain-oil                     0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
290 O    Cottonseed-oil                     0.025000       1.000  0.020 Field
 Full comment: Field trial data 1/2 LOQ
291 O    Cottonseed-meal                    0.025000       1.000  0.020 Field
 Full comment: Field trial data 1/2 LOQ
293 O    Peanuts-oil                        0.006500       1.000  1.000 PDP 20
 Full comment: PDP 2000 peanut butter 1/2 LOQ
310 O    Peppermint                         2.730000       1.000  0.220 US. EP
 Full comment: US. EPA field trial data
311 O    Peppermint-oil                     2.730000       1.000  0.220 US. EP
 Full comment: US. EPA field trial data
312 O    Spearmint                          4.730000       1.000  0.220 US. EP
 Full comment: US. EPA field trial data
313 O    Spearmint-oil                      4.730000       1.000  0.220 US. EP
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Full comment: US. EPA field trial data
315 O Grapes-wine and sherry 0.010000 1.000 1.000 PDP 98
Full comment: PDP 98-99 CA grape juice 1/2 LOQ
318 D Milk-nonfat solids 0.015000 1.000 1.000 PDP 96
Full comment: PDP 96-98 whole milk CA 1/2 LOQ
319 D Milk-fat solids 0.015000 1.000 1.000 PDP 96
Full comment: PDP 96-98 whole milk CA 1/2 LOQ
320 D Milk sugar (lactose) 0.015000 1.000 1.000 PDP 96
Full comment: PDP 96-98 whole milk CA 1/2 LOQ
321 M Beef-meat byproducts 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
322 M Beef-other organ meats 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
323 M Beef-dried 0.004300 1.920 1.000 PDP 20
Full comment: PDP 2001 beef muscle 1/2 LOQ
324 M Beef-fat w/o bones 0.012000 1.000 1.000 PDP 20
Full comment: PDP 2001 beef adipose 1/2 LOQ
325 M Beef-kidney 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
326 M Beef-liver 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
327 M Beef-lean (fat/free) w/o bones 0.004300 1.000 1.000 PDP 20
Full comment: PDP 2001 beef muscle 1/2 LOQ
328 M Goat-meat byproducts 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
329 M Goat-other organ meats 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
330 M Goat-fat w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
331 M Goat-kidney 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
332 M Goat-liver 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
333 M Goat-lean (fat/free) w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
334 M Horsemeat 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
336 M Sheep-meat byproducts 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
337 M Sheep-other organ meats 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
338 M Sheep-fat w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
339 M Sheep-kidney 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
340 M Sheep-liver 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
341 M Sheep-lean (fat free) w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
342 M Pork-meat byproducts 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
343 M Pork-other organ meats 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
344 M Pork-fat w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
345 M Pork-kidney 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
346 M Pork-liver 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
347 M Pork-lean (fat free) w/o bone 0.050000 1.000 1.000 1/2 U.

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 Full comment: 1/2 U.S. EPA tolerance
355 P    Turkey-byproducts                  0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
356 P    Turkey-giblets (liver)             0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
357 P    Turkey--fat w/o bones              0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
358 P    Turkey- lean/fat free w/o bones    0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
360 P    Poultry-other-lean (fat free) w/   0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
361 P    Poultry-other-giblets(liver)       0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
362 P    Poultry-other-fat w/o bones        0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
363 P    Eggs-whole                         0.050000       1.000  1.000 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
364 P    Eggs-white only                    0.050000       1.000  1.000 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
365 P    Eggs-yolk only                     0.050000       1.000  1.000 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
366 P    Chicken-byproducts                 0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
367 P    Chicken-giblets(liver)             0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
368 P    Chicken-fat w/o bones              0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
369 P    Chicken-lean/fat free w/o bones    0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
385 P    Chicken-giblets (excl. liver)      0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
388 15   Corn grain/sugar-molasses          0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
392 O    Grapes-juice-concentrate           0.010000       3.000  1.000 PDP 98
 Full comment: PDP 98-99 CA grape juice 1/2 LOQ
398 D    Milk-based water                   0.015000       1.000  1.000 PDP 96
 Full comment: PDP 96-98 whole milk CA 1/2 LOQ
403 O    Peanuts-butter                     0.006500       1.000  1.000 PDP 20
 Full comment: PDP 2000 peanut butter 1/2 LOQ
418 2    Sweet potatos-leaves               0.010000       1.000  0.020 PDP CA
 Full comment: PDP CA sweet potato 1/2 LOQ
420 10   Tangerines-juice-concentrate       0.010000       3.200  1.000 PDP CA
 Full comment: PDP CA orange juice 1/2 LOQ as surrogate
424 M    Veal-fat w/o bones                 0.012000       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef adipose 1/2 LOQ
425 M    Veal-lean (fat free) w/o bones     0.004300       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef muscle 1/2 LOQ
426 M    Veal-kidney                        0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
427 M    Veal-liver                         0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
428 M    Veal-other organ meats             0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
429 M    Veal-dried                         0.004300       1.920  1.000 PDP 20
 Full comment: PDP 2001 beef muscle 1/2 LOQ
430 M    Veal-meat byproducts               0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
431 14   Walnut oil                         0.050000       1.000  0.250 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
441 10   Grapefruit-juice-concentrate       0.010000       3.930  0.020 PDP or
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 Full comment: PDP orange juice 1/2 LOQ as surrogate
442 10   Lemons-juice-concentrate          0.010000       5.700  1.000 PDP CA
 Full comment: PDP CA orange juice 1/2 LOQ as surrogate
443 10   Limes-juice-concentrate           0.010000       3.000  1.000 PDP CA
 Full comment: PDP CA orange juice 1/2 LOQ as surrogate
448 10   Grapefruit peel                   2.500000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
449 P    Turkey-other organ meats          0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
940 O    Peanuts-hulled                    0.006500       1.000  1.000 PDP 20
 Full comment: PDP 2000 peanut butter 1/2 LOQ
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California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Chronic.RS7
Adjustment factor #2 used.
Analysis Date 11-06-2003/15:14:38 Residue file dated: 11-06-2003/15:11:58/14
Reference dose (RfD, Chronic) = .04 mg/kg bw/day
NOEL (Chronic) = 3.8 mg/kg bw/day

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000183	20,805	0.5%
U.S. Population (spring season)	0.000182	20,866	0.5%
U.S. Population (summer season)	0.000182	20,843	0.5%
U.S. Population (autumn season)	0.000185	20,491	0.5%
U.S. Population (winter season)	0.000180	21,058	0.5%
Northeast region	0.000187	20,299	0.5%
Midwest region	0.000189	20,058	0.5%
Southern region	0.000168	22,615	0.4%
Western region	0.000194	19,538	0.5%
Hispanics	0.000221	17,231	0.6%
Non-hispanic whites	0.000176	21,646	0.4%
Non-hispanic blacks	0.000182	20,933	0.5%
Non-hisp/non-white/non-black	0.000212	17,963	0.5%
All infants (< 1 year)	0.000224	16,975	0.6%
Nursing infants	0.000071	53,814	0.2%
Non-nursing infants	0.000282	13,474	0.7%
Children 1-6 yrs	0.000595	6,388	1.5%
Children 7-12 yrs	0.000298	12,762	0.7%
Females 13-19 (not preg or nursing)	0.000135	28,243	0.3%
Females 20+ (not preg or nursing)	0.000108	35,146	0.3%
Females 13-50 yrs	0.000115	33,046	0.3%
Females 13+ (preg/not nursing)	0.000160	23,694	0.4%
Females 13+ (nursing)	0.000162	23,516	0.4%
Males 13-19 yrs	0.000181	20,983	0.5%
Males 20+ yrs	0.000122	31,065	0.3%
Seniors 55+	0.000112	33,785	0.3%

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Chronic.RS7
Adjustment factor #2 used.
Analysis Date 11-06-2003/15:16:00 Residue file dated: 11-06-2003/15:11:58/14
Q* = 0.0059

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Lifetime risk (Q*= .0059)
U.S. Population (total)	0.000183	1.08E-06
U.S. Population (spring season)	0.000182	1.07E-06
U.S. Population (summer season)	0.000182	1.08E-06
U.S. Population (autumn season)	0.000185	1.09E-06
U.S. Population (winter season)	0.000180	1.06E-06
Northeast region	0.000187	1.10E-06
Midwest region	0.000189	1.12E-06
Southern region	0.000168	9.91E-07
Western region	0.000194	1.15E-06
Hispanics	0.000221	1.30E-06
Non-hispanic whites	0.000176	1.04E-06
Non-hispanic blacks	0.000182	1.07E-06
Non-hisp/non-white/non-black	0.000212	1.25E-06
All infants (< 1 year)	0.000224	1.32E-06
Nursing infants	0.000071	4.17E-07
Non-nursing infants	0.000282	1.66E-06
Children 1-6 yrs	0.000595	3.51E-06
Children 7-12 yrs	0.000298	1.76E-06
Females 13-19 (not preg or nursing)	0.000135	7.94E-07
Females 20+ (not preg or nursing)	0.000108	6.38E-07
Females 13-50 yrs	0.000115	6.78E-07
Females 13+ (preg/not nursing)	0.000160	9.46E-07
Females 13+ (nursing)	0.000162	9.53E-07
Males 13-19 yrs	0.000181	1.07E-06
Males 20+ yrs	0.000122	7.22E-07
Seniors 55+	0.000112	6.64E-07

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Chronic.RS7
Adjustment factor #2 used.
Analysis Date 11-06-2003/15:15:20 Residue file dated: 11-06-2003/15:11:58/14
Q* = 0.026

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Lifetime risk (Q*= .026)
U.S. Population (total)	0.000183	4.75E-06
U.S. Population (spring season)	0.000182	4.73E-06
U.S. Population (summer season)	0.000182	4.74E-06
U.S. Population (autumn season)	0.000185	4.82E-06
U.S. Population (winter season)	0.000180	4.69E-06
Northeast region	0.000187	4.87E-06
Midwest region	0.000189	4.93E-06
Southern region	0.000168	4.37E-06
Western region	0.000194	5.06E-06
Hispanics	0.000221	5.73E-06
Non-hispanic whites	0.000176	4.56E-06
Non-hispanic blacks	0.000182	4.72E-06
Non-hisp/non-white/non-black	0.000212	5.50E-06
All infants (< 1 year)	0.000224	5.82E-06
Nursing infants	0.000071	1.84E-06
Non-nursing infants	0.000282	7.33E-06
Children 1-6 yrs	0.000595	1.55E-05
Children 7-12 yrs	0.000298	7.74E-06
Females 13-19 (not preg or nursing)	0.000135	3.50E-06
Females 20+ (not preg or nursing)	0.000108	2.81E-06
Females 13-50 yrs	0.000115	2.99E-06
Females 13+ (preg/not nursing)	0.000160	4.17E-06
Females 13+ (nursing)	0.000162	4.20E-06
Males 13-19 yrs	0.000181	4.71E-06
Males 20+ yrs	0.000122	3.18E-06
Seniors 55+	0.000112	2.92E-06

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE 1994-98 data
Residue file: H:\MyFiles\DEEM Files\Propargite\propargite water chronic.RS7
Adjust. #2 NOT used
Analysis Date 10-30-2004 Residue file dated: 10-29-2003/17:03:34/14
Reference dose (RfD) = 0.04 (NOEL) = 3.8 mg/kg bw/day

Food Code	Crop Grp	Food Name	RESIDUE (ppm)	Adj.Factors #1	#2	Comment
432	O	Water-bottled	0.000089	1.000	1.000	DPR su
		Full comment: DPR surface water data				
433	O	Water-tap	0.000089	1.000	1.000	DPR su
		Full comment: DPR surface water data				
434	O	Water-commercial processing	0.000089	1.000	1.000	DPR su
		Full comment: DPR surface water data				
435	O	Water-non-food based	0.000089	1.000	1.000	DPR su
		Full comment: DPR surface water data				

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\propargite water chronic.RS7
Adjustment factor #2 NOT used.
Analysis Date 10-30-2003/15:45:10 Residue file dated: 10-29-2003/17:03:34/14
Reference dose (RfD, Chronic) = .04 mg/kg bw/day
NOEL (Chronic) = 3.8 mg/kg bw/day

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000003	>1,000,000	0.0%
U.S. Population (spring season)	0.000003	>1,000,000	0.0%
U.S. Population (summer season)	0.000003	>1,000,000	0.0%
U.S. Population (autumn season)	0.000003	>1,000,000	0.0%
U.S. Population (winter season)	0.000003	>1,000,000	0.0%
Northeast region	0.000002	>1,000,000	0.0%
Midwest region	0.000003	>1,000,000	0.0%
Southern region	0.000003	>1,000,000	0.0%
Western region	0.000003	>1,000,000	0.0%
Hispanics	0.000003	>1,000,000	0.0%
Non-hispanic whites	0.000003	>1,000,000	0.0%
Non-hispanic blacks	0.000003	>1,000,000	0.0%
Non-hisp/non-white/non-black	0.000003	>1,000,000	0.0%
All infants (< 1 year)	0.000009	405,071	0.0%
Nursing infants	0.000003	>1,000,000	0.0%
Non-nursing infants	0.000012	325,772	0.0%
Children 1-6 yrs	0.000004	>1,000,000	0.0%
Children 7-12 yrs	0.000003	>1,000,000	0.0%
Females 13-19 (not preg or nursing)	0.000002	>1,000,000	0.0%
Females 20+ (not preg or nursing)	0.000002	>1,000,000	0.0%
Females 13-50 yrs	0.000002	>1,000,000	0.0%
Females 13+ (preg/not nursing)	0.000002	>1,000,000	0.0%
Females 13+ (nursing)	0.000003	>1,000,000	0.0%
Males 13-19 yrs	0.000002	>1,000,000	0.0%
Males 20+ yrs	0.000002	>1,000,000	0.0%
Seniors 55+	0.000002	>1,000,000	0.0%

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\propargite water chronic.RS7
Adjustment factor #2 NOT used.
Analysis Date 10-30-2003/15:45:51 Residue file dated: 10-29-2003/17:03:34/14
Q* = 0.0059

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Lifetime risk (Q*= .0059)
U.S. Population (total)	0.000003	1.55E-08
U.S. Population (spring season)	0.000003	1.57E-08
U.S. Population (summer season)	0.000003	1.66E-08
U.S. Population (autumn season)	0.000003	1.49E-08
U.S. Population (winter season)	0.000003	1.49E-08
Northeast region	0.000002	1.39E-08
Midwest region	0.000003	1.61E-08
Southern region	0.000003	1.52E-08
Western region	0.000003	1.70E-08
Hispanics	0.000003	1.72E-08
Non-hispanic whites	0.000003	1.52E-08
Non-hispanic blacks	0.000003	1.52E-08
Non-hisp/non-white/non-black	0.000003	1.75E-08
All infants (< 1 year)	0.000009	5.53E-08
Nursing infants	0.000003	1.98E-08
Non-nursing infants	0.000012	6.88E-08
Children 1-6 yrs	0.000004	2.18E-08
Children 7-12 yrs	0.000003	1.52E-08
Females 13-19 (not preg or nursing)	0.000002	1.25E-08
Females 20+ (not preg or nursing)	0.000002	1.41E-08
Females 13-50 yrs	0.000002	1.43E-08
Females 13+ (preg/not nursing)	0.000002	1.40E-08
Females 13+ (nursing)	0.000003	1.76E-08
Males 13-19 yrs	0.000002	1.44E-08
Males 20+ yrs	0.000002	1.42E-08
Seniors 55+	0.000002	1.28E-08

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\propargite water chronic.RS7
Adjustment factor #2 NOT used.
Analysis Date 10-30-2003/15:46:11 Residue file dated: 10-29-2003/17:03:34/14
Q* = 0.026

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Lifetime risk (Q*= .026)
U.S. Population (total)	0.000003	6.84E-08
U.S. Population (spring season)	0.000003	6.91E-08
U.S. Population (summer season)	0.000003	7.33E-08
U.S. Population (autumn season)	0.000003	6.55E-08
U.S. Population (winter season)	0.000003	6.57E-08
Northeast region	0.000002	6.13E-08
Midwest region	0.000003	7.08E-08
Southern region	0.000003	6.68E-08
Western region	0.000003	7.49E-08
Hispanics	0.000003	7.56E-08
Non-hispanic whites	0.000003	6.71E-08
Non-hispanic blacks	0.000003	6.70E-08
Non-hisp/non-white/non-black	0.000003	7.71E-08
All infants (< 1 year)	0.000009	2.44E-07
Nursing infants	0.000003	8.75E-08
Non-nursing infants	0.000012	3.03E-07
Children 1-6 yrs	0.000004	9.63E-08
Children 7-12 yrs	0.000003	6.71E-08
Females 13-19 (not preg or nursing)	0.000002	5.52E-08
Females 20+ (not preg or nursing)	0.000002	6.23E-08
Females 13-50 yrs	0.000002	6.29E-08
Females 13+ (preg/not nursing)	0.000002	6.16E-08
Females 13+ (nursing)	0.000003	7.75E-08
Males 13-19 yrs	0.000002	6.33E-08
Males 20+ yrs	0.000002	6.27E-08
Seniors 55+	0.000002	5.66E-08

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE 1994-98 data
Residue file: H:\MyFiles\DEEM Files\Propargite\Propargite Aggregate Chronic.RS7
Adjust. #2 used
Analysis Date 11-06-2003 Residue file dated: 11-06-2003/15:13:34/14
Reference dose (RfD) = 0.04 (NOEL) = 3.8 mg/kg bw/day

Food Code	Crop Grp	Food Name	RESIDUE (ppm)	Adj.Factors #1	#2	Comment
13	O	Grapes	0.005100	1.000	1.000	PDP CA
		Full comment: PDP CA grapes				
14	O	Grapes-raisins	0.008000	4.300	1.000	PDP CA
		Full comment: PDP CA grapes w/ different PCT				
15	O	Grapes-juice	0.010000	1.000	1.000	PDP CA
		Full comment: PDP CA grape juice 1/2 LOQ				
22	10	Grapefruit-peeled fruit	0.010000	1.000	0.020	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
23	10	Grapefruit-juice	0.010000	1.000	0.020	PDP CA
		Full comment: PDP CA orange juice 1/2 LOQ as surrogate				
26	10	Lemons-peeled fruit	0.020000	1.000	0.010	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
27	10	Lemons-peel	2.500000	1.000	0.010	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
28	10	Lemons-juice	0.010000	1.000	1.000	PDP CA
		Full comment: PDP CA orange juice 1/2 LOQ as surrogate				
30	10	Limes-peeled fruit	0.010000	1.000	0.010	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
31	10	Limes-peel	2.500000	1.000	0.010	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
32	10	Limes-juice	0.010000	1.000	1.000	PDP CA
		Full comment: PDP CA orange juice 1/2 LOQ as surrogate				
33	10	Oranges-juice-concentrate	0.010000	3.720	1.000	PDP 97
		Full comment: PDP 97-98 CA orange juice 1/2 LOQ				
34	10	Oranges-peeled fruit	0.010000	1.000	0.020	PDP 96
		Full comment: PDP 96, 00-01 CA orange 1/2 LOQ				
35	10	Oranges-peel	2.500000	1.000	0.020	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
36	10	Oranges-juice	0.010000	1.000	1.000	PDP 97
		Full comment: PDP 97-98 CA orange juice 1/2 LOQ				
38	10	Tangerines	0.010000	1.000	0.020	PDP CA
		Full comment: PDP CA orange 1/2 LOQ as surrogate				
39	10	Tangerines-juice	0.010000	1.000	1.000	PDP CA
		Full comment: PDP CA orange juice 1/2 LOQ as surrogate				
40	14	Almonds	0.050000	1.000	0.350	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
48	14	Walnuts	0.050000	1.000	0.250	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
64	12	Nectarines	0.128000	1.000	1.000	PDP CA
		Full comment: PDP CA nectarines				
113	O	Tea	5.000000	1.000	0.060	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
125	O	Hops	7.500000	1.000	0.050	1/2 U.
		Full comment: 1/2 U.S. EPA tolerance				
195	O	Grapes-leaves	0.005100	1.000	1.000	PDP CA
		Full comment: PDP CA grapes				
207	1C	Potatoes/white-whole	0.010000	1.000	0.020	PDP 20
		Full comment: PDP 2000-2001 potato CA 1/2 LOQ				
208	1C	Potatoes/white-unspecified	0.010000	1.000	0.020	PDP 20

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 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
209 1C   Potatoes/white-peeled              0.010000       1.000  0.020 PDP 20
 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
210 1C   Potatoes/white-dry                 0.010000       6.500  0.020 PDP 20
 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
211 1C   Potatoes/white-peel only           0.010000       1.000  0.020 PDP 20
 Full comment: PDP 2000-2001 potato CA 1/2 LOQ
218 1CD  Sweet potatoes (incl yams)         0.010000       1.000  0.020 PDP CA
 Full comment: PDP CA sweet potato 1/2 LOQ
227 6C   Beans-dry-great northern           0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
228 6C   Beans-dry-kidney                   0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
229 6C   Beans-dry-lima                     0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
230 6C   Beans-dry-navy (pea)               0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
231 6C   Beans-dry-other                    0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
232 6C   Beans-dry-pinto                    0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
237 15   Corn/pop                           0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
238 15   Corn/sweet                         0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ
244 6C   Mung beans (sprouts)               0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
249 6C   Beans-dry-broadbeans               0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
251 6C   Beans-dry-pigeon beans             0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
256      Beans-dry-hyacinth                 0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
258 6C   Beans-dry-blackeye peas/cowpea     0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
259 6C   Beans-dry-garbanzo/chick pea       0.100000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
266 15   Corn grain-endosperm               0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
267 15   Corn grain-bran                    0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
268 15   Corn grain/sugar/hfcs              0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
275 15   Sorghum (including milo)           5.000000       1.000  0.010 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
289 15   Corn grain-oil                     0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
290 O    Cottonseed-oil                     0.025000       1.000  0.020 Field
 Full comment: Field trial data 1/2 LOQ
291 O    Cottonseed-meal                    0.025000       1.000  0.020 Field
 Full comment: Field trial data 1/2 LOQ
293 O    Peanuts-oil                        0.006500       1.000  1.000 PDP 20
 Full comment: PDP 2000 peanut butter 1/2 LOQ
310 O    Peppermint                         2.730000       1.000  0.220 US. EP
 Full comment: US. EPA field trial data
311 O    Peppermint-oil                     2.730000       1.000  0.220 US. EP
 Full comment: US. EPA field trial data
312 O    Spearmint                          4.730000       1.000  0.220 US. EP
 Full comment: US. EPA field trial data
313 O    Spearmint-oil                      4.730000       1.000  0.220 US. EP
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Full comment: US. EPA field trial data
315 O Grapes-wine and sherry 0.010000 1.000 1.000 PDP CA
Full comment: PDP CA grape juice 1/2 LOQ
318 D Milk-nonfat solids 0.015000 1.000 1.000 PDP 96
Full comment: PDP 96-98 whole milk CA 1/2 LOQ
319 D Milk-fat solids 0.015000 1.000 1.000 PDP 96
Full comment: PDP 96-98 whole milk CA 1/2 LOQ
320 D Milk sugar (lactose) 0.015000 1.000 1.000 PDP 96
Full comment: PDP 96-98 whole milk CA 1/2 LOQ
321 M Beef-meat byproducts 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
322 M Beef-other organ meats 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
323 M Beef-dried 0.004300 1.920 1.000 PDP 20
Full comment: PDP 2001 beef muscle 1/2 LOQ
324 M Beef-fat w/o bones 0.012000 1.000 1.000 PDP 20
Full comment: PDP 2001 beef adipose 1/2 LOQ
325 M Beef-kidney 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
326 M Beef-liver 0.004800 1.000 1.000 PDP 20
Full comment: PDP 2001 beef liver 1/2 LOQ
327 M Beef-lean (fat/free) w/o bones 0.004300 1.000 1.000 PDP 20
Full comment: PDP 2001 beef muscle 1/2 LOQ
328 M Goat-meat byproducts 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
329 M Goat-other organ meats 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
330 M Goat-fat w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
331 M Goat-kidney 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
332 M Goat-liver 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
333 M Goat-lean (fat/free) w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
334 M Horsemeat 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
336 M Sheep-meat byproducts 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
337 M Sheep-other organ meats 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
338 M Sheep-fat w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
339 M Sheep-kidney 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
340 M Sheep-liver 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
341 M Sheep-lean (fat free) w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
342 M Pork-meat byproducts 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
343 M Pork-other organ meats 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
344 M Pork-fat w/o bone 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
345 M Pork-kidney 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
346 M Pork-liver 0.050000 1.000 1.000 1/2 U.
Full comment: 1/2 U.S. EPA tolerance
347 M Pork-lean (fat free) w/o bone 0.050000 1.000 1.000 1/2 U.

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 Full comment: 1/2 U.S. EPA tolerance
355 P    Turkey-byproducts                  0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
356 P    Turkey-giblets (liver)             0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
357 P    Turkey--fat w/o bones              0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
358 P    Turkey- lean/fat free w/o bones    0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
360 P    Poultry-other-lean (fat free) w/   0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
361 P    Poultry-other-giblets(liver)       0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
362 P    Poultry-other-fat w/o bones        0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
363 P    Eggs-whole                         0.050000       1.000  1.000 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
364 P    Eggs-white only                    0.050000       1.000  1.000 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
365 P    Eggs-yolk only                     0.050000       1.000  1.000 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
366 P    Chicken-byproducts                 0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
367 P    Chicken-giblets(liver)             0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
368 P    Chicken-fat w/o bones              0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
369 P    Chicken-lean/fat free w/o bones    0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
385 P    Chicken-giblets (excl. liver)      0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
388 15   Corn grain/sugar-molasses          0.010000       1.000  0.010 PDP sw
 Full comment: PDP sweet corn 1/2 LOQ as surrogate
392 O    Grapes-juice-concentrate           0.010000       3.000  1.000 PDP CA
 Full comment: PDP CA grape juice 1/2 LOQ
398 D    Milk-based water                   0.015000       1.000  1.000 PDP 96
 Full comment: PDP 96-98 whole milk CA 1/2 LOQ
403 O    Peanuts-butter                     0.006500       1.000  1.000 PDP 20
 Full comment: PDP 2000 peanut butter 1/2 LOQ
418 2    Sweet potatos-leaves               0.010000       1.000  0.020 PDP CA
 Full comment: PDP CA sweet potato 1/2 LOQ
420 10   Tangerines-juice-concentrate       0.010000       3.200  1.000 PDP CA
 Full comment: PDP CA orange juice 1/2 LOQ as surrogate
424 M    Veal-fat w/o bones                 0.012000       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef adipose 1/2 LOQ
425 M    Veal-lean (fat free) w/o bones     0.004300       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef muscle 1/2 LOQ
426 M    Veal-kidney                        0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
427 M    Veal-liver                         0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
428 M    Veal-other organ meats             0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
429 M    Veal-dried                         0.004300       1.920  1.000 PDP 20
 Full comment: PDP 2001 beef muscle 1/2 LOQ
430 M    Veal-meat byproducts               0.004800       1.000  1.000 PDP 20
 Full comment: PDP 2001 beef liver 1/2 LOQ
431 14   Walnut oil                         0.050000       1.000  0.250 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
432 O    Water-bottled                      0.000089       1.000  1.000 DPR su
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 Full comment: DPR surface water data
433 O    Water-tap                          0.000089       1.000  1.000 DPR su
 Full comment: DPR surface water data
434 O    Water-commercial processing        0.000089       1.000  1.000 DPR su
 Full comment: DPR surface water data
435 O    Water-non-food based               0.000089       1.000  1.000 DPR su
 Full comment: DPR surface water data
441 10   Grapefruit-juice-concentrate       0.010000       3.930  0.020 PDP CA
 Full comment: PDP CA orange juice 1/2 LOQ as surrogate
442 10   Lemons-juice-concentrate           0.010000       5.700  1.000 PDP CA
 Full comment: PDP CA orange juice 1/2 LOQ as surrogate
443 10   Limes-juice-concentrate            0.010000       3.000  1.000 PDP CA
 Full comment: PDP CA orange juice 1/2 LOQ as surrogate
448 10   Grapefruit peel                    2.500000       1.000  0.020 1/2 U.
 Full comment: 1/2 U.S. EPA tolerance
449 P    Turkey-other organ meats           0.016500       1.000  1.000 PDP 20
 Full comment: PDP 2000-2001 poultry 1/2 LOQ
940 O    Peanuts-hulled                     0.006500       1.000  1.000 PDP 20
 Full comment: PDP 2000 peanut butter 1/2 LOQ
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California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Aggregate Chronic.RS7
Adjustment factor #2 used.
Analysis Date 11-06-2003/15:19:16 Residue file dated: 11-06-2003/15:13:34/14
Reference dose (RfD, Chronic) = .04 mg/kg bw/day
NOEL (Chronic) = 3.8 mg/kg bw/day

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000185	20,509	0.5%
U.S. Population (spring season)	0.000185	20,566	0.5%
U.S. Population (summer season)	0.000185	20,526	0.5%
U.S. Population (autumn season)	0.000188	20,217	0.5%
U.S. Population (winter season)	0.000183	20,767	0.5%
Northeast region	0.000190	20,047	0.5%
Midwest region	0.000192	19,774	0.5%
Southern region	0.000171	22,275	0.4%
Western region	0.000197	19,253	0.5%
Hispanics	0.000223	17,007	0.6%
Non-hispanic whites	0.000178	21,332	0.4%
Non-hispanic blacks	0.000184	20,640	0.5%
Non-hisp/non-white/non-black	0.000215	17,715	0.5%
All infants (< 1 year)	0.000233	16,293	0.6%
Nursing infants	0.000074	51,367	0.2%
Non-nursing infants	0.000294	12,939	0.7%
Children 1-6 yrs	0.000599	6,348	1.5%
Children 7-12 yrs	0.000300	12,652	0.8%
Females 13-19 (not preg or nursing)	0.000137	27,804	0.3%
Females 20+ (not preg or nursing)	0.000111	34,384	0.3%
Females 13-50 yrs	0.000117	32,365	0.3%
Females 13+ (preg/not nursing)	0.000163	23,348	0.4%
Females 13+ (nursing)	0.000165	23,090	0.4%
Males 13-19 yrs	0.000184	20,705	0.5%
Males 20+ yrs	0.000125	30,464	0.3%
Seniors 55+	0.000115	33,144	0.3%

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Aggregate Chronic.RS7
Adjustment factor #2 used.
Analysis Date 11-06-2003/15:20:15 Residue file dated: 11-06-2003/15:13:34/14
Q* = 0.0059

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Lifetime risk (Q*= .0059)
U.S. Population (total)	0.000185	1.09E-06
U.S. Population (spring season)	0.000185	1.09E-06
U.S. Population (summer season)	0.000185	1.09E-06
U.S. Population (autumn season)	0.000188	1.11E-06
U.S. Population (winter season)	0.000183	1.08E-06
Northeast region	0.000190	1.12E-06
Midwest region	0.000192	1.13E-06
Southern region	0.000171	1.01E-06
Western region	0.000197	1.16E-06
Hispanics	0.000223	1.32E-06
Non-hispanic whites	0.000178	1.05E-06
Non-hispanic blacks	0.000184	1.09E-06
Non-hisp/non-white/non-black	0.000215	1.27E-06
All infants (< 1 year)	0.000233	1.38E-06
Nursing infants	0.000074	4.36E-07
Non-nursing infants	0.000294	1.73E-06
Children 1-6 yrs	0.000599	3.53E-06
Children 7-12 yrs	0.000300	1.77E-06
Females 13-19 (not preg or nursing)	0.000137	8.06E-07
Females 20+ (not preg or nursing)	0.000111	6.52E-07
Females 13-50 yrs	0.000117	6.93E-07
Females 13+ (preg/not nursing)	0.000163	9.60E-07
Females 13+ (nursing)	0.000165	9.71E-07
Males 13-19 yrs	0.000184	1.08E-06
Males 20+ yrs	0.000125	7.36E-07
Seniors 55+	0.000115	6.76E-07

California Department of Pesticide Regulation Ver. 7.81
DEEM Chronic analysis for PROPARGITE (1994-98 data)
Residue file name: H:\MyFiles\DEEM Files\Propargite\Propargite Aggregate Chronic.RS7
Adjustment factor #2 used.
Analysis Date 11-06-2003/15:19:48 Residue file dated: 11-06-2003/15:13:34/14
Q* = 0.026

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Lifetime risk (Q*= .026)
U.S. Population (total)	0.000185	4.82E-06
U.S. Population (spring season)	0.000185	4.80E-06
U.S. Population (summer season)	0.000185	4.81E-06
U.S. Population (autumn season)	0.000188	4.89E-06
U.S. Population (winter season)	0.000183	4.76E-06
Northeast region	0.000190	4.93E-06
Midwest region	0.000192	5.00E-06
Southern region	0.000171	4.44E-06
Western region	0.000197	5.13E-06
Hispanics	0.000223	5.81E-06
Non-hispanic whites	0.000178	4.63E-06
Non-hispanic blacks	0.000184	4.79E-06
Non-hisp/non-white/non-black	0.000215	5.58E-06
All infants (< 1 year)	0.000233	6.06E-06
Nursing infants	0.000074	1.92E-06
Non-nursing infants	0.000294	7.64E-06
Children 1-6 yrs	0.000599	1.56E-05
Children 7-12 yrs	0.000300	7.81E-06
Females 13-19 (not preg or nursing)	0.000137	3.55E-06
Females 20+ (not preg or nursing)	0.000111	2.87E-06
Females 13-50 yrs	0.000117	3.05E-06
Females 13+ (preg/not nursing)	0.000163	4.23E-06
Females 13+ (nursing)	0.000165	4.28E-06
Males 13-19 yrs	0.000184	4.77E-06
Males 20+ yrs	0.000125	3.24E-06
Seniors 55+	0.000115	2.98E-06

APPENDIX C

Peer Review Comments and Response

Office of Environmental Health Hazard Assessment

Joan E. Denton, Ph.D., Director
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Oakland Office • Mailing Address: 1515 Clay Street, 16th Floor • Oakland, California 94612

MEMORANDUM

Terry Tamminen
Agency Secretary

Arnold Schwarzenegger
Governor

TO: Gary Patterson, Ph.D., Chief
Medical Toxicology Branch
Department of Pesticide Regulation
P.O. Box 4015
Sacramento, California 95812-4015

FROM: Anna M. Fan, Ph.D., Chief
Pesticide and Environmental Toxicology Section
1515 Clay Street, 16th Floor
Oakland, California 946122

DATE: August 26, 2004

SUBJECT: COMMENTS ON THE FINAL DRAFT RISK CHARACTERIZATION DOCUMENT FOR THE ACTIVE INGREDIENT PROPARGITE PREPARED BY THE DEPARTMENT OF PESTICIDE REGULATION

Thank you for the opportunity to review the draft risk characterization document (RCD) for propargite prepared by the Department of Pesticide Regulation (DPR). The Office of Environmental Health Hazard Assessment (OEHHA) reviews risk assessments prepared by DPR under the general authority of the Health and Safety Code, Section 59004, and also under the Food and Agricultural Code (FAC), Section 13129, in which OEHHA has the authority to provide advice, consultation, and recommendations to DPR concerning the risks to human health associated with exposure to pesticide active ingredients.

Propargite is an organosulfur miticide/acaricide used for the control of mites on a variety of bearing and non-bearing agricultural crops, as well as non-food agricultural sites. Bearing crops include grapes, citrus, nectarines, peanuts, almonds, and mint; non-bearing crops include cherries, grapefruit and navel oranges; non-food agricultural sites include roses and evergreen conifers. There are no registered residential uses for propargite. Nearly one million pounds of propargite was applied in California in 2002.

We note that the registrant voluntarily canceled a number of uses of propargite in 1996 due to unacceptable dietary cancer risks. Indeed, propargite is listed by Proposition 65 as a carcinogen and as a reproductive toxicant. U.S. EPA considers propargite a B2 (probable human) carcinogen based on the appearance of rare jejunal tumors in both sexes of rats following chronic oral exposure.

DPR initiated this risk assessment to address potential adverse health effects for the general public as a result of the remaining registered uses of propargite. This version of the RCD evaluates dietary and drinking water exposures to the general public. An addendum is planned that will address aggregate exposures to propargite from occupational, diet, water and ambient air sources.

Overall, we find the RCD for propargite to be appropriate, comprehensive and well written. Accordingly, our comments focus on a relatively few areas of concern:

1. OEHHA is concerned that because the chronic "no observed adverse effect level" (NOAEL) of 3.8 mg/kg-day used in the RCD is higher than the acute NOAEL of 2 mg/kg, protection against acute developmental effects is not sufficient. A NOAEL of 2 mg/kg from a rabbit developmental study based on anorexia in dams and delayed ossification of the skull in offspring at the next higher dose of 6 mg/kg was used in the RCD for evaluating acute exposures to propargite (Serota et al., 1983). We note that the NOAEL selected for evaluating chronic exposures was 3.8 mg/kg-day from a rat study and was based on reductions in body weights and food consumption at the next higher dose of 19.2 mg/kg-day (Trutter, 1991). Clearly, the chronic NOAEL is insufficient to protect against the acute or subchronic effects observed in the rabbit studies. Accordingly, OEHHA suggests the adoption of 2 mg/kg-day (or 1 mg/kg-day from the dermal study in rabbits; see comment #2, below) from the developmental study in rabbits for the evaluation of chronic exposures to propargite.

2. Systemic effects in adult animals may also not be sufficiently protected against if a chronic NOAEL of 3.8 mg/kg-day is adopted. A systemic NOAEL of 1 mg/kg-day was observed in a 21-day dermal study in rabbits (Bailey, 1987). This NOAEL was based on reduced body weights, changes in clinical chemistry and hematological values, and increased relative liver and kidney weights observed at the next higher dose of 10 mg/kg-day. It is mentioned in the RCD that "the veterinary pathologist for the study suggested that the hematological and clinical chemistry changes may be due to dermal irritation" (with a LOAEL of 0.1 mg/kg-day). OEHHA finds this insufficient justification for discounting the systemic NOAEL of 1 mg/kg-day and, similar to the case in comment #1 above, we believe that there may be insufficient protection against systemic effects (reduced body weights, increased relative liver and kidney weights and changes in clinical chemistry and hematological values) in the evaluation of chronic exposures to propargite presented in the RCD. Accordingly, we suggest adding additional discussion supporting the conclusion that the observed systemic effects are secondary to dermal irritation. If appropriate justification is not possible, then OEHHA recommends adopting 1 mg/k-day for evaluating chronic exposures to propargite.

3. Subchronic/seasonal exposures to propargite were not evaluated in the RCD. The rationale provided was that "No seasonal exposure to propargite is anticipated since dietary and drinking water exposure to propargite did not vary significantly with season." We assume this to mean that because exposure to propargite does not appreciably vary over the course of a year, it is not necessary to evaluate seasonal exposures. OEHHA disagrees since seasonal exposures are estimated differently than acute and chronic exposures (e.g., different assumptions regarding chemical concentrations in food and environmental media, and seasonal qualitative and quantitative changes in food consumption), it is important that subchronic exposure is characterized and evaluated. Accordingly, OEHHA recommends adding this evaluation to the RCD.

4. Acute Margins of Exposure (MOEs) for combined dietary and drinking water exposures range from 290 for children aged 1 to 6 years old to 1,200 for non-nursing pregnant females >13 years old. Although greater than 100, the level typically associated with a potential health concern, they are relatively low, particularly considering that four levels of refinement to the dietary exposure analysis were required to arrive at acceptable MOEs. Accordingly, monitoring for propargite residues (since the bulk of the aggregate exposure is dietary) in California crops should be intensified and closely followed.

5. There is a significant difference between the values used by U.S. EPA and DPR for surface water concentrations in evaluating carcinogenic risk. U.S. EPA used a value of 8.7 ppb in their calculations while DPR applied a value of 0.089 ppb. The value used by U.S. EPA resulted in the calculation of an unacceptable carcinogenicity drinking water risk ($> 1 \times 10^{-6}$ risk). The differences in water concentrations result from the use of a different dataset by DPR than the one used by U.S. EPA. We note that in the most recent version of the Reregistration Eligibility Decision (RED) for propargite, U.S. EPA (2001) states (page 16) that because their earlier modeling was very conservative and because of labeling changes regarding propargite applications near surface water agreed to by the registrant their remaining concerns regarding carcinogenic risk are largely mitigated. Nevertheless, on page 19 of the RED, U.S. EPA continues to express some concern about carcinogenic risk from propargite in surface water. It is yet to be shown that the measures specified by the labeling change will actually reduce surface water concentrations to levels below that pose an unacceptable cancer risk. The registrant has agreed to conduct a drinking water study to verify the adequacy of the labeling changes. OEHHA recommends that DPR participate in this study and verifies that the results do indeed confirm that actual residues of propargite fall below levels of concern for carcinogenic effects. If the mitigation measures prove ineffective, OEHHA

recommends that DPR develop additional mitigation measures to further protect surface waters from propargite contamination

6. Tolerance assessment for propargite yielded acute dietary MOEs significantly less than 100 (<10 for some population subgroups) for oranges, grapes, grapefruit, and nectarines. Residues on these commodities near the legal tolerance level are therefore of potential health concern. OEHHA urges DPR to advise U.S. EPA of this potential public health issue and request that propargite tolerances on oranges, grapes, grapefruit, and nectarines be reevaluated.

Again, thank you for the opportunity to review this document and we hope that you find our comments useful. We look forward to our review of the addendums to this document that evaluate occupational exposure and aggregate exposures that include residues in ambient air as a source of exposure to propargite. Should you have any questions regarding OEHHA's review of this RCD, please contact Dr. David Rice at (916) 324-1277 (primary reviewer), Mr. Robert Schlag at (916) 323-2624, or me at (510) 622-3165.

cc: Val F. Siebal
Chief Deputy Director
Office of Environmental Health Hazard Assessment

George V. Alexeeff, Ph.D., D.A.B.T.
Deputy Director for Scientific Affairs
Office of Environmental Health Hazard Assessment

Robert D. Schlag, M.Sc., Chief
Pesticide Epidemiology Unit
Pesticide and Environmental Toxicology Section
Office of Environmental Health Hazard Assessment

David W. Rice, Ph.D.
Pesticide and Food Toxicology Unit
Pesticide and Environmental Toxicology Section
Office of Environmental Health Hazard Assessment

References

Bailey DE (Hazelton Laboratories America, Inc.) (1987). 21-Day dermal toxicity study in rabbits. Uniroyal Chemical Co., Inc. DPR Vol. 259-093, Rec. No. 72509.

Serota DG, Wolfe GW, Durloo RS, and Fezio WL (Hazelton Laboratories America Inc.), (1983). Teratology study in rabbits - Omite Technical (Revised Final Report). Uniroyal Chemical Co., Inc. DPR Vol. 259-042, Rec. No. 35303.

Trutter JA (Hazelton Laboratories America, Inc.) (1991). Combined chronic toxicity and oncogenicity study in rats with Omite® technical. Uniroyal Chemical Co., Inc. DPR Vol. 259-128, pts 1-10, Rec. No. 89293.

U.S. EPA (2001). Reregistration Eligibility Decision (RED) for Propargite. Case No. 0243. Office of Pesticide Programs, U.S. Environmental Protection Agency. September 28, 2001. 139pp. (http://www.epa.gov/oppsrrd1/REDs/propargite_red.pdf).

Department of Pesticide Regulation

Mary-Ann Warmerdam
Director

Arnold Schwarzenegger
Governor

MEMORANDUM

TO: Gary Patterson, Ph.D.
Supervising Toxicologist
Medical Toxicology Branch

VIA: Keith Pfeifer
Senior Toxicologist
Medical Toxicology Branch

FROM: Carolyn Lewis
Associate Toxicologist
Medical Toxicology Branch

DATE: October 4, 2004

SUBJECT: RESPONSE TO OEHHA'S COMMENTS REGARDING THE PROPARGITE RISK CHARACTERIZATION DOCUMENT

Thank you for the comments regarding the Risk Characterization Document (RCD) for propargite (dated July 9, 2004) addressing dietary and drinking water exposure. The following comments are in response to OEHHA's comments (dated August 26, 2004) regarding this RCD:

1. ***(OEHHA)*** *OEHHA is concerned that because the chronic "no observed adverse effect level" (NOAEL) of 3.8 mg/kg-day used in the RCD is higher than the acute NOAEL of 2 mg/kg, protection against acute developmental effects is not sufficient. A NOAEL of 2 mg/kg from a rabbit developmental study based on anorexia in dams and delayed ossification of the skull in offspring at the next higher dose of 6 mg/kg was used in the RCD for evaluating acute exposures to propargite (Serota et al., 1983). We note that the NOAEL selected for evaluating chronic exposures was 3.8 mg/kg-day from a rat study and was based on reductions in body weights and food consumption at the next higher dose of 19.2 mg/kg-day (Trutter, 1991). Clearly, the chronic NOAEL is insufficient to protect against the acute or subchronic effects observed in the rabbit studies. Accordingly, OEHHA suggests the adoption of 2 mg/kg-day (or 1 mg/kg-day from the dermal study in rabbits; see comment #2, below) from the developmental study in rabbits for the evaluation of chronic exposures to propargite.*

   (DPR) The lowest chronic NOEL of 3.8 mg/kg/day which was observed in the 2-year rat study conducted by Trutter (1991) is technically higher than the NOEL of 2 mg/kg/day in the rabbit developmental toxicity study conducted by Serota *et al.* (1983); however, the difference in these NOELs is small and could easily be the result of dose selection. Furthermore, a higher NOEL of 6 mg/kg/day was observed in a subsequent rabbit developmental toxicity study conducted by Schardein (1989) raising some question about the findings of the study conducted by Serota *et al.* (1983). The lowest chronic margin of

exposure (MOE) is greater than 6,000 for dietary exposure and greater than 300,000 for drinking water exposure. Consequently, use of the lower NOEL will not alter the bottom-line conclusion of this risk assessment for these exposure scenarios and only add confusion by using a short-term NOEL to evaluate long-term dietary and drinking water exposure. Therefore, the chronic NOEL was not changed in this risk assessment.

2. ***(OEHHA)*** *Systemic effects in adult animals may also not be sufficiently protected against if a chronic NOAEL of 3.8 mg/kg-day is adopted. A systemic NOAEL of 1 mg/kg-day was observed in a 21-day dermal study in rabbits (Bailey, 1987). This NOAEL was based on reduced body weights, changes in clinical chemistry and hematological values, and increased relative liver and kidney weights observed at the next higher dose of 10 mg/kg-day. It is mentioned in the RCD that "the veterinary pathologist for the study suggested that the hematological and clinical chemistry changes may be due to dermal irritation" (with a LOAEL of 0.1 mg/kg-day). OEHHA finds this insufficient justification for discounting the systemic NOAEL of 1 mg/kg-day and, similar to the case in comment #1 above, we believe that there may be insufficient protection against systemic effects (reduced body weights, increased relative liver and kidney weights and changes in clinical chemistry and hematological values) in the evaluation of chronic exposures to propargite presented in the RCD. Accordingly, we suggest adding additional discussion supporting the conclusion that the observed systemic effects are secondary to dermal irritation. If appropriate justification is not possible, then OEHHA recommends adopting 1 mg/k-day for evaluating chronic exposures to propargite.*

(DPR) The 21-day rabbit dermal toxicity study conducted by Bailey (1987) was not used to evaluate chronic dietary exposure because of the route of exposure. There is sufficient reason to suspect that some of the systemic effects seen in the Bailey study were due to the severe dermal irritation that was seen. Most of the systemic effects in this study were changes in hematological, clinical chemistry values and organ weight changes which are of uncertain toxicological significance without associated gross and histopathological lesions. The only gross and histopathological lesions observed in this study were related to the skin, except for hepatic necrosis which was only observed at the highest dose level in one male and one female. None of the clinical chemistry changes were those associated with liver toxicity. Even the body weight reductions could be related to the severe dermal irritation. This study will be used to evaluate occupational dermal exposure, but it is my professional judgment that it is not appropriate to use it for evaluating dietary or drinking water exposure.

3. ***(OEHHA)*** *Subchronic/seasonal exposures to propargite were not evaluated in the RCD. The rationale provided was that "No seasonal exposure to propargite is anticipated since dietary and drinking water exposure to propargite did not vary significantly with season." We assume this to mean that because exposure to propargite does not*

appreciably vary over the course of a year, it is not necessary to evaluate seasonal exposures. OEHHA disagrees since seasonal exposures are estimated differently than acute and chronic exposures (e.g., different assumptions regarding chemical concentrations in food and environmental media, and seasonal qualitative and quantitative changes in food consumption), it is important that subchronic exposure is characterized and evaluated. Accordingly, OEHHA recommends adding this evaluation to the RCD.

(DPR) DPR has not traditionally done seasonal dietary exposure analyses. It is unclear what different assumptions would be used regarding chemical concentrations in food or the environment that would be taken into consideration with seasonal dietary exposure. Currently we do not get the collection date for the PDP residue data from USDA, so we cannot easily determine if there is any variation in residues for a commodity between seasons. As far as seasonal quantitative changes in consumption, the DEEM software has no separate seasonal dietary exposure analysis; however, the chronic dietary exposure analysis does include a breakdown of the exposure for the U.S. population as a whole by season. Generally, when a pesticide has uses on more than a few commodities, the exposure doesn't vary significantly from season to season because when exposure to one or more commodity decreases due to reduced consumption, the exposure to other commodities will increase in their place. For propargite, the seasonal averages for the U.S. population from the DEEM chronic dietary exposure analysis showed only a slight variation from a low of 0.183 µg/kg/day in winter to a high of 0.188 µg/kg/day in autumn. Hardly a difference worth doing a separate seasonal exposure analysis. Finally, it is unclear what qualitative differences in consumption OEHHA anticipates with seasonal exposure and how that should be taken into consideration in a seasonal dietary exposure assessment.

4. ***(OEHHA)*** *Acute Margins of Exposure (MOEs) for combined dietary and drinking water exposures range from 290 for children aged 1 to 6 years old to 1,200 for non-nursing pregnant females >13 years old. Although greater than 100, the level typically associated with a potential health concern, they are relatively low, particularly considering that four levels of refinement to the dietary exposure analysis were required to arrive at acceptable MOEs. Accordingly, monitoring for propargite residues (since the bulk of the aggregate exposure is dietary) in California crops should be intensified and closely followed.*

(DPR) Budgetary constraints have resulted in DPR reducing the amount of monitoring it has done in recent years. Given the current budgetary situation, it is unlikely that situation will change any time soon. Furthermore, DPR residue monitoring is not considered as accurate as PDP residue monitoring because the limits of detection are lower with the PDP program and commodities are peeled as they would normally be

eaten in the PDP program. DPR monitoring is performed primarily for enforcement purposes to see if tolerances have been exceeded, not for risk assessment purposes.

5. ***(OEHHA)*** *There is a significant difference between the values used by U.S. EPA and DPR for surface water concentrations in evaluating carcinogenic risk. U.S. EPA used a value of 8.7 ppb in their calculations while DPR applied a value of 0.089 ppb. The value used by U.S. EPA resulted in the calculation of an unacceptable carcinogenicity drinking water risk (> 1 x 10^{-6} risk). The differences in water concentrations result from the use of a different dataset by DPR than the one used by U.S. EPA. We note that in the most recent version of the Reregistration Eligibility Decision (RED) for propargite, U.S. EPA (2001) states (page 16) that because their earlier modeling was very conservative and because of labeling changes regarding propargite applications near surface water agreed to by the registrant their remaining concerns regarding carcinogenic risk are largely mitigated. Nevertheless, on page 19 of the RED, U.S. EPA continues to express some concern about carcinogenic risk from propargite in surface water. It is yet to be shown that the measures specified by the labeling change will actually reduce surface water concentrations to levels below that pose an unacceptable cancer risk. The registrant has agreed to conduct a drinking water study to verify the adequacy of the labeling changes. OEHHA recommends that DPR participate in this study and verifies that the results do indeed confirm that actual residues of propargite fall below levels of concern for carcinogenic effects. If the mitigation measures prove ineffective, OEHHA recommends that DPR develop additional mitigation measures to further protect surface waters from propargite contamination*

(DPR) U.S. EPA used a model to derive the drinking water levels of comparison they used in their risk assessment. DPR used actual surface water residues collected in California which we considered preferable to a theoretical value derived from a model whose assumptions may or may not be relevant for California. U.S. EPA states in their propargite risk assessment that "modeling is generally considered to be an unrefined assessment and provides high-end estimates". We considered our drinking water analysis for propargite to be more refined than U.S. EPA's, although even our assessment may have exaggerated the risks because it is not known if the any of the surface water monitored is used for drinking water. Furthermore, it is not known if the propargite residues would remain after water treatment. Finally, it should be noted that 288 actual drinking water samples from New York and California was analyzed for propargite by the PDP program in 2001 and no residues were found. Although more realistic, DPR choose to use the surface water residue data as a worse case scenario. If the exposures were unacceptable assuming these residues were present, then the exposure assessment would be further refined using the PDP. This refinement was not necessary even to address concerns about carcinogenic risks. Although DPR would certainly be interested in reviewing the results of the water monitoring conducted by the registrant, the registrant

References

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